# EXHIBIT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 1 - 2014

Samuel S. Epstein, M.D.
Cancer Prevention Coalition
University of Illinois at Chicago
School of Public Health, MC 922
2121 West Taylor Street, Rm. 322
Chicago, Illinois 60612

RE: Docket Numbers 94P-0420 and FDA-2008-P-0309-0001/CP

Dear Dr. Epstein:

This letter is in response to your two Citizen Petitions dated November 17, 1994 and May 13, 2008, requesting that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products. Your 1994 Petition requests that all cosmetic talc bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." Additionally, your 2008 Petition requests that cosmetic talcum powder products bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." Further, both of your Petitions specifically request, pursuant to 21 CFR 10.30(h)(2), a hearing for you to present scientific evidence in support of this petition.

We have carefully considered both of your Petitions. We are committed to the protection of the public health and share your interest in reducing the risk of ovarian cancer. Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate scientific basis on reasonable grounds.

After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

For this reason and for the additional reasons described below, FDA is denying your Petitions.

**I. Discussion**

The basis of your request, throughout both Petitions, can be summarized as comprising three major points:

1. Talc may be associated with asbestos.
2. Talc is a carcinogen based on the findings of a 1993 National Toxicology Program study.
3. Epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As the points you raise in your Petitions concern the chemistry and toxicology of talc, the epidemiology associated with talc use, and the etiology of ovarian cancer, commensurate reviews were conducted to assess your request.

Chemistry Findings:

Asbestos is a known carcinogen and your first major point is that talc may be associated with asbestos. As evidence that talc cosmetic products contain asbestos, you first cite a 1968 survey of 22 talcum products that found fiber content averaging 19% in all 22 products. This author further concludes that "the fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits …"

You then cite a follow up study from 1971-1975 that examined 21 samples of consumer talcums and powder and concluded that cosmetic grade talc was not used exclusively in these products. This study found the presence of asbestiform anthophyllite and tremolite, chrysotile, and quartz. From these two citations, one may infer that currently available talc-containing cosmetic products are presently contaminated with asbestos, a known carcinogen. Unfortunately, you did not present any original data on the chemical composition of talc currently being used in cosmetics talc products or data linking these findings to currently used talc.

It has been reported in the scientific literature that most talc products in world trade are impure as a result of the geological processes involved in the formation of talc deposits. Further, talc containing asbestos fibers such as tremolite asbestos or chrysotile are sometimes encountered. However, large deposits of high purity, asbestos-free talc do exist and talc purification techniques have been developed which can be used to improve talc quality. Thus, while it has been reported in the past that cosmetic talc has been contaminated with asbestos, it has been also reported that asbestos-free talc deposits do exist. In addition, techniques do exist for the purification of talc in order to improve its quality. You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed, since the data submitted is almost 40 years old.

Because safety questions about the possible presence of asbestos in talc are raised periodically, in 2009 FDA conducted an exploratory survey of currently marketed cosmetic-grade raw material talc and finished cosmetic products containing talc. This survey analyzed cosmetic-grade raw material talc from four suppliers out of a possible group of nine suppliers we had requested talc samples from, along with thirty-four talc-containing cosmetic products currently available in the Washington, D.C. metropolitan area for the presence of asbestos. In order to cover as broad a product range as possible, samples identified for testing included low, medium, and high priced products, along with some from "niche" markets. The cosmetic products identified as containing talc included eye shadow, blush, foundation, face powder, and body powder.

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. While FDA found this data informative, the results were limited by the fact that only four suppliers submitted samples and by the number of products tested. They do not prove that all talc-containing cosmetic products currently marketed in the United States are free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health. You may wish to see more on this survey on our website at http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm.

Toxicology Findings:

Your second major point is that talc is a carcinogen with or without the presence of asbestos-like fibers. The basis to this claim is that in 1993, the National Toxicology Program (NTP) published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.

This NTP report concluded that cosmetic-grade talc caused tumors in animals, even though no asbestos-like fibers were found. The report made the following observations:

- There was some evidence of carcinogenic activity in non-asbestiform talc from inhalation studies in male rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland.
- There was clear evidence of carcinogenic activity of talc in female rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.
- There was no evidence of carcinogenic activity of talc in male or female mice exposed to 6 or 18 mg/cubic meter.

However, this study lacks convincing scientific support because of serious flaws in its design and conduct, including:

- The investigators used micronized talc instead of consumer-grade talc resulting in the experimental protocol not being reflective of human exposure conditions in terms of particle size.

- Investigators conceded that they had problems with the aerosol generation system; whereby, the target aerosol concentrations were either excessive or not maintained during 26 of the 113-122 weeks of the study.
- The study did not include positive and negative dust controls which would have permitted an "exact assessment" of the talc's carcinogenicity relative to the two control dusts.

In light of these shortcomings, a panel of experts at the 1994 ISRTP/FDA workshop declared that the 1993 NTP study has no relevance to human risk.

In addition, we reviewed relevant toxicity literature (consisting of 15 articles from 1980 to 2008), not cited in your Petitions, to determine if there was additional support at this point in time to for your suggested warning label. Scientific literature on studies of acute exposure effects, subchronic exposure effects, chronic exposure or carcinogenicity effects, developmental or reproductive toxicity, and genotoxicity effects were reviewed. As a result of the review of this relevant literature, FDA did not find enough additional support at this point in time for your suggested warning label.

Epidemiology and Etiology Findings:

Your third major point is that epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

After consideration of the scientific literature submitted in support of both Citizen Petitions, FDA found:

1 The exposure to talc is not well-characterized; it is not known if the talc referred to in the scientific studies was free of asbestos contamination; various consumer brands or lots of talc were not identified; and contamination of talc by asbestiform minerals or other structurally similar compounds was not ruled out.

2 Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk.

3 Results of case-controls studies do not demonstrate a consistent positive association across studies; some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0 and dose-response evidence is lacking.

4 A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and

5 there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure.

6 The conclusion of the International Agency for Research on Cancer that epidemiological studies provide limited evidence for the carcinogenicity of perineal use of talc based body powder and the IARC classification of body-powder talc as group-2B, a possible carcinogen to human beings, is persuasive, but the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer.

Per the etiology review, approximately 10% of epithelial ovarian cancers are associated with inherited mutations. The remaining 90% of epithelial ovarian cancers are not related to these genetic mutations are non-hereditary. They have been historically classified based on histology as borderline/low malignant potential, serous, endometrioid, mucinous, and clear-cell.

Two theories have historically dominated on the cause of epithelial ovarian cancer and these are the "incessant ovulation hypothesis" and the "gonadotropin hypothesis." In addition to these endogenous factors, the role of exogenous factors via retrograde transport of noxious substances (e.g. carcinogens, particulates such as talc and asbestos, endometriosis and infectious agents) from the vagina and uterus into the Fallopian Tubes and peritoneal cavity have been studied extensively as a possible risk factor for ovarian cancer.

While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers. However, there has been no conclusive evidence to support causality.

The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking.

Request for hearing

In addition to your request for a warning label, you also requested a hearing, under 21 CFR 10.30(h)(2), so that you can present scientific evidence in support of your petitions.

Under this regulation, FDA may deny a citizen petition request for a hearing if the data and information submitted (even if accurate), are insufficient to justify the determination urged. In consideration of your request, we conducted an expanded literature search dating from the filing of the petition in 2008 through January 2014. The results of this search failed to identify any new compelling literature data or new scientific evidence.

Since we find that the data and information are insufficient to justify the determination you request and we did not identify any new compelling literature data or new scientific evidence, FDA is also denying your hearing request.

**II. Conclusion**

FDA appreciates the goals of the Cancer Prevention Coalition and FDA supports the goal of reducing the rate of ovarian cancer. Although FDA is denying the Cancer Prevention Coalition's petitions for the reasons discussed above, the Agency shares your commitment to the public health.

Sincerely,

Steven M. Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition

Drafted: J. Gasper, OCAC, 2/28/14
Comments: L. Katz, OCAC, 3/3/14
Revised: J. Gasper, OCAC, 3/4/14
Cleared: N.Sadrieh, OCAC, 3/4/14
Cleared: LMKatz, OCAC, 3/5/14
Reviewed: FHogue, OCAC: 3/614
Cleared by:Musser:3/13/14
F/T:SRussell, OCAC 3/18/14

# EXHIBIT 2

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION**<br>Steven J. Kim, Individually and O/B/O the Estate Lynda Bondurant, Plaintiff,<br>v.<br>Johnson & Johnson, Johnson & Johnson Consumer Inc., , Defendants. | **MDL NO. 16-2738 (FLW) (LHG) JUDGE FREDA L. WOLFSON MAG. JUDGE LOIS H. GOODMAN**<br>AMENDED COMPLAINT AND JURY DEMAND<br>3:19-cv-14366<br>Civil Action No.:<br>DIRECT FILED ACTION |

# FIRST AMENDED SHORT FORM COMPLAINT AND JURY DEMAND

The Plaintiff(s) named below file(s) this *Short Form Complaint and Demand for Jury Trial* against Defendants named below by and through the undersigned counsel. Plaintiff(s) incorporate(s) by reference the allegations contained in *Plaintiffs' Master Long Form Complaint* in *In re: Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation*, MDL No. 2738 in the United States District Court for the District of New Jersey. Plaintiff(s) file(s) this Short Form Complaint as permitted by Case Management Order No. 1 of this Court.

In addition to those causes of action contained in *Plaintiffs' Master Long Form Complaint*, where certain claims require specific pleadings and/or

amendments, Plaintiff(s) shall add and include them herein.

## IDENTIFICATION OF PARTIES

### Identification of Plaintiff(s)

1. Name of individual injured due to the use of talcum powder product(s): Lynda Bondurant.

2. At the time of the filing of the specific case, Plaintiff(s) is/are a citizen of Louisiana.

3. Consortium Claim(s): The following individual(s) allege damages for loss of consortium: Steven J. Kim

4. Survival and/or Wrongful Death Claims:

Name and residence of Decedent Plaintiff when she suffered the talcum powder product(s) related death: Lynda Bondurant 927 Francis Street, New Orleans, LA 70117

5. Plaintiff/Decedent was born on 10/2/1959 and died on 10/22/2020.

6. Plaintiff is filing this case in a representative capacity as the Husband of the Plaintiff, having been duly appointed as the Administrator of the Estate by the Civil District Court of Parish of Orleans on March 17, 2021, Judge Robin Giarrusso.

7. As a result of using talcum powder products, Plaintiff/Decedent suffered personal and economic injur(ies) that are alleged to have been caused by the use of the products identified in Paragraph 16 below, but not limited to, the following:

X injury to herself

X injury to the person represented

X wrongful death

X survivorship action

X economic loss

X loss of services

X loss of consortium

____ other: _____

_____

**Identification of Defendants**

8. Plaintiff(s)/Decedent Plaintiff(s) is/are suing the following Defendant(s) (please check all that apply)[1]:

☑ Johnson & Johnson

☑ Johnson & Johnson Consumer Inc.

[1] If additional Counts and/or Counts directed to other Defendants are alleged by the specific Plaintiff(s) as to whom this *Short Form Complaint* applies, the specific facts supporting these allegations must be pleaded by the Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure, and the Defendants against whom they are alleged must be specifically identified on a separate sheet of paper attached to this *Short Form Complaint*.

- ☐ Imerys Talc America, Inc. ("Imerys Talc")
- ☐ Personal Care Products Council ("PCPC")

**Additional Defendants:**

☐ Other(s) Defendant(s) (please specify):_____

_____

_____

## JURISDICTION & VENUE

**Jurisdiction:**

9. Jurisdiction in this Short Form Complaint is based on:

- ☑ Diversity of Citizenship
- ☐ Other (The basis of any additional ground for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure). _____

_____

**Venue:**

10. District Court(s) and Division (if any) in which venue was proper where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court and to where remand could be ordered by the Judicial Panel for trial:

USDC EDLA

_____

_____

## CASE SPECIFIC FACTS

11. Plaintiff(s) currently reside(s) in (City, State):

New Orleans, Louisiana.

12. At the time of the Plaintiff's/Decedent's diagnosis with a talcum powder product(s) injury, Plaintiff/Decedent resided in (City, State):

New Orleans, Louisiana.

13. The Plaintiff/Decedent was diagnosed with a talcum powder product(s) injury in (City/State): New Orleans, LA on October 2018 (date).

14. To the best of Plaintiff's knowledge, Plaintiff/Decedent began using talcum powder product(s) on or about the following date: 1959 and continued the use of talcum powder product(s) through about the following date: 2018.

15. The Plaintiff/Decedent purchased talcum powder product(s) in the following (State(s)): LOUISIANA.

16. Plaintiff/Decedent used the following talcum powder products:

- ☑ Johnson & Johnson's Baby Powder
- ☐ Shower to Shower

## CAUSES OF ACTION

17. Plaintiff(s) hereby adopt(s) and incorporate(s) by reference the *Master Long Form Complaint and Jury Demand* as if fully set forth herein.

18. The following claims and allegations asserted in the Master *Long Form Complaint and Jury Demand* are herein adopted by reference by Plaintiff(s):

- ☐ Count I: Products Liability – Strict Liability – Failure to Warn (Against Imerys Talc)
- ☑ Count II: Products Liability – Strict Liability – Failure to Warn (Against the Johnson & Johnson Defendants)
- ☐ Count III: Products Liability – Strict Liability – Defective Manufacturer and Design (Against Imerys Talc)
- ☑ Count IV: Products Liability – Strict Liability – Defective Manufacturer and Design (Against the Johnson & Johnson Defendants)
- ☑ Count V: Breach of Express Warranties (Against the Johnson & Johnson Defendants)
- ☑ Count VI: Breach of Implied Warranty of Merchantability (Against the Johnson & Johnson Defendants)
- ☑ Count VII: Breach of Implied Warranty of Fitness for a Particular Purpose (Against the Johnson & Johnson Defendants)
- ☐ Count VIII: Negligence (Against Imerys Talc)
- ☑ Count IX: Negligence (Against the Johnson & Johnson Defendants)
- ☐ Count X: Negligence (Against PCPC)
- ☑ Count XI: Negligent Misrepresentation (Against the Johnson &

Johnson Defendants)

☑ Count XII: Fraud (Against the Johnson & Johnson Defendants)

☐ Count XIII: Fraud (Against PCPC)

☑ Count XIV: Violation of State Consumer Protection Laws of the State of LOUISIANA (Against the Johnson & Johnson Defendants).

☐ Count XV: Fraudulent Concealment (Against Imerys Talc)

☑ Count XVI: Fraudulent Concealment (Against the Johnson & Johnson Defendants)

☐ Count XVII: Fraudulent Concealment (Against PCPC)

☑ Count XVIII: Civil Conspiracy (Against All Defendants)

☑ Count XIX: Loss of Consortium (Against All Defendants)

☑ Count XX: Punitive Damages (Against All Defendants)

☑ Count XXI: Discovery Rule and Tolling (Against All Defendants)

☑ Count XXII: Wrongful Death (Against All Defendants)

☑ Count XXIII: Survival Action (Against All Defendants)

☑ Furthermore, Plaintiff(s) assert(s) the following additional theories and/or State Causes of Action against Defendant(s) identified in Paragraph nine (9) above. If Plaintiff(s) includes additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pled by Plaintiff(s) in a manner complying with the requirements

of the Federal Rules of Civil Procedure. _____

Johnson Baby Powder contains a vice or defect that renders it useless or its use so inconvenient that consumers would not have purchased it had they known about the vice or defect. Pursuant to Louisiana Civil Code Article 2520, a seller warrants the buyer against redhibitory defects, or vices, in the thing sold. Johnson's Baby Powder, which is sold and promoted by Defendants, possesses redhibitory defects because it is unreasonable dangerous, which render Johnson's Baby Powder useless or so inconvenient that it must be presumed that Plaintiff would not have bought or used Johnson's Baby Powder products had she known of the defects.

**WHEREFORE**, Plaintiff(s) pray(s) for relief and judgment against Defendants of compensatory damages, punitive damages, interest, costs of suit, and such further relief as the Court deems equitable and just, and as set forth in the Master Long Form Complaint as appropriate.

## JURY DEMAND

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

Dated: June 17, 2021

Respectfully Submitted by,

s/Andrew J Geiger
Andrew J. Geiger, Esq. Bar #32467
Allan Berger, Esq. Bar #2977
Allan Berger and Associates
4173 Canal Street
New Orleans, La 70119
Phone: 504-486-9481
Fax: 504-483-8130
aberger@bergerlawnola.com

**Counsel for Plaintiff(s)**

# EXHIBIT 3

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION** | **MDL NO. 16-2738 (FLW) (LHG)**<br>**JUDGE FREDA L. WOLFSON**<br>**MAG. JUDGE LOIS H. GOODMAN** |
| HILARY CONVERSE AND MARQUIS CONVERSE,<br><br>Plaintiff,<br><br>v.<br><br>JOHNSON & JOHNSON, INC., JOHNSON & JOHNSON CONSUMER, INC.<br><br>Defendants. | COMPLAINT AND JURY DEMAND<br><br>Civil Action No.: 3:18-cv-17586<br><br>DIRECT FILED ACTION |

**AMENDED SHORT FORM COMPLAINT AND JURY DEMAND**

The Plaintiff(s) named below file(s) this *Amended Short Form Complaint and Demand for Jury Trial* against Defendants named below by and through the undersigned counsel. Plaintiff(s) incorporate(s) by reference the allegations contained in *Plaintiffs' Master Long Form Complaint* in *In re: Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation*, MDL No. 2738 in the United States District Court for the District of New Jersey. Plaintiff(s) file(s) this Short Form Complaint as permitted by Case Management Order No. 1 of this Court.

In addition to those causes of action contained in *Plaintiffs' Master Long Form Complaint*, where certain claims require specific pleadings and/or amendments, Plaintiff(s) shall add and include them herein.

## IDENTIFICATION OF PARTIES

**Identification of Plaintiff(s)**

1. Name of individual injured due to the use of talcum powder product(s): Hilary Converse

2. At the time of the filing of the specific case, Plaintiff(s) is/are a citizen of New Haven County, CT.

3. Consortium Claim(s): The following individual(s) allege damages for loss of consortium: Marquis Converse.

4. Survival and/or Wrongful Death Claims:

   Name and residence of Decedent Plaintiff when she suffered the talcum powder product(s) related death: _____

   _____

5. Plaintiff/Decedent was born on 1948 and died on _____.

6. Plaintiff is filing this case in a representative capacity as the _____ of the _____, having been duly appointed as the _____ by the _____ Court of _____.

7. As a result of using talcum powder products, Plaintiff/Decedent suffered personal and economic injur(ies) that are alleged to have been caused by the use of the products identified in Paragraph 16 below, but not limited to, the following:

   X injury to herself

   _____ injury to the person represented

_____ wrongful death

_____ survivorship action

X economic loss

X loss of services

X loss of consortium

_____ other:_____

**Identification of Defendants**

8. Plaintiff(s)/Decedent Plaintiff(s) is/are suing the following Defendant(s) (please check all that apply)[1]

☒ Johnson & Johnson

☒ Johnson & Johnson Consumer Inc.

☐ Imerys Talc America, Inc. ("Imerys Talc") was named as a Defendant in Plaintiff's initial complaint filed on December 26, 2018. In accordance with the Stay Order issued in the Imerys bankruptcy filed February 13,2 019, in the United States Bankruptcy Court for the District of Delaware, Plaintiff's Amended Complaint is not intended in any way to act as a commencement or continuation of the action as against Imerys Talc America, Inc. as a Defendant, nor is it intended to dismiss, abandon, amend, modify, or withdraw any claims or allegations made against Imerys Talc America, Inc. as a Defendant. Plaintiff reserves the right to seek leave to amend upon the lifting of the Stay or other action by the Bankruptcy Court permitting continuation of Plaintiff's action against Imerys.

☐ Personal Care Products Council ("PCPC")

**Additional Defendants:**

[1] If additional Counts and/or Counts directed to other Defendants are alleged by the specific Plaintiff(s) as to whom this *Short Form Complaint* applies, the specific facts supporting these allegations must be pleaded by the Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure, and the Defendants against whom they are alleged must be specifically identified on a separate sheet of paper attached to this *Short Form Complaint*.

☐ Other(s) Defendant(s) (please specify):_____

## JURISDICTION & VENUE

**Jurisdiction:**

9. Jurisdiction in this Short Form Complaint is based on:

☒ Diversity of Citizenship

☐ Other (The basis of any additional ground for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure).

**Venue:**

10. District Court(s) and Division (if any) in which venue was proper where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court and to where remand could be ordered by the Judicial Panel for trial: United States District Court for the District of Connecticut.

## CASE SPECIFIC FACTS

11. Plaintiff(s) currently reside(s) in (City, State): Beacon Falls, CT.

12. At the time of the Plaintiff's/Decedent's diagnosis with a talcum powder product(s) injury, Plaintiff/Decedent resided in (City, State): Beacon Falls, CT.

13. The Plaintiff/Decedent was diagnosed with a talcum powder product(s) injury in (City, State): New Haven, CT. on or about September 2007.

14. To the best of Plaintiff's knowledge, Plaintiff/Decedent began using talcum powder product(s) on or about the following date: 1962 and continued the use of talcum powder product(s) through about the following date: 2006.

15. The Plaintiff/Decedent purchased talcum powder product(s) in the following State(s): Connecticut.

16. Plaintiff/Decedent used the following talcum powder products:

☒ Johnson & Johnson's Baby Powder

☐ Shower to Shower

## CAUSES OF ACTION

17. Plaintiff(s) hereby adopt(s) and incorporate(s) by reference the *Master Long Form Complaint and Jury Demand* as if fully set forth herein.

18. The following claims and allegations asserted in the *Master Long Form Complaint and Jury Demand* are herein adopted by reference by Plaintiff(s):

☐ Count I: Products Liability – Strict Liability – Failure to Warn (Against Imerys Talc) was named as a Defendant in Plaintiff's initial complaint filed on December 26, 2018. In accordance with the Stay Order issued in the Imerys bankruptcy filed February 13,2 019, in the United States Bankruptcy Court for the District of Delaware, Plaintiff's Amended Complaint is not intended in any way to act as a commencement or continuation of the action as against Imerys Talc America, Inc. as a Defendant, nor is it intended to dismiss, abandon, amend, modify, or withdraw any claims or allegations made against Imerys Talc America, Inc. as a Defendant. Plaintiff reserves the right to seek leave to amend upon the lifting of the Stay or other action by the Bankruptcy Court permitting continuation of Plaintiff's action against Imerys.

☒ Count II: Products Liability – Strict Liability – Failure to Warn (Against the Johnson & Johnson Defendants)

☐ Count III: Products Liability – Strict Liability– Defective Manufacturer and Design (Against Imerys Talc) was named as a Defendant in Plaintiff's initial complaint filed on December 26, 2018. In accordance with the Stay Order issued in the Imerys bankruptcy filed February 13,2 019, in the United States Bankruptcy Court for the District of Delaware, Plaintiff's Amended Complaint is not intended in any way to act as a commencement or

continuation of the action as against Imerys Talc America, Inc. as a Defendant, nor is it intended to dismiss, abandon, amend, modify, or withdraw any claims or allegations made against Imerys Talc America, Inc. as a Defendant. Plaintiff reserves the right to seek leave to amend upon the lifting of the Stay or other action by the Bankruptcy Court permitting continuation of Plaintiff's action against Imerys.

☒ Count IV: Products Liability – Strict Liability – Defendant Manufacturer and Design (Against the Johnson & Johnson Defendants)

☒ Count V: Breach of Express Warranties (Against the Johnson & Johnson Defendants)

☒ Count VI: Breach of Implied Warranty of Merchantability (Against the Johnson & Johnson Defendants)

☒ Count VII: Breach of Implied Warranty of Fitness for a Particular Purpose (Against the Johnson & Johnson Defendants)

☐ Count VIII: Negligence (Against Imerys Talc) was named as a Defendant in Plaintiff's initial complaint filed on December 26, 2018. In accordance with the Stay Order issued in the Imerys bankruptcy filed February 13,2 019, in the United States Bankruptcy Court for the District of Delaware, Plaintiff's Amended Complaint is not intended in any way to act as a commencement or continuation of the action as against Imerys Talc America, Inc. as a Defendant, nor is it intended to dismiss, abandon, amend, modify, or withdraw any claims or allegations made against Imerys Talc America, Inc. as a Defendant. Plaintiff reserves the right to seek leave to amend upon the lifting of the Stay or other action by the Bankruptcy Court permitting continuation of Plaintiff's action against Imerys.

☐

☒ Count IX: Negligence (Against the Johnson &

Johnson Defendants)

☐ Count X: Negligence (Against PCPC)

☒ Count XI: Negligent Misrepresentation (Against the Johnson & Johnson Defendants)

☒ Count XII: Fraud (Against the Johnson & Johnson Defendants)

☐ Count XIII: Fraud (Against PCPC)

☒ Count XIV: Violation of State Consumer Protection Laws of the State(s) of Connecticut (Against the Johnson & Johnson Defendants)

☐ Count XV: Fraudulent Concealment (Against Imerys Talc) was named as a Defendant in Plaintiff's initial complaint filed on December 26, 2018. In accordance with the Stay Order issued in the Imerys bankruptcy filed February 13,2 019, in the United States Bankruptcy Court for the District of Delaware, Plaintiff's Amended Complaint is not intended in any way to act as a commencement or continuation of the action as against Imerys Talc America, Inc. as a Defendant, nor is it intended to dismiss, abandon, amend, modify, or withdraw any claims or allegations made against Imerys Talc America, Inc. as a Defendant. Plaintiff reserves the right to seek leave to amend upon the lifting of the Stay or other action by the Bankruptcy Court permitting continuation of Plaintiff's action against Imerys.

☒ Count XVI: Fraudulent Concealment (Against the Johnson & Johnson Defendants)

☐ Count XVII: Fraudulent Concealment (Against PCPC)

☒ Count XVIII: Civil Conspiracy (Against All Defendants)

☒ Count XIX: Loss of Consortium (Against All

Defendants)

☒ Count XX: Punitive Damages (Against All Defendants)

☒ Count XXI: Discovery Rule and Tolling (Against All Defendants)

☐ Count XXII: Wrongful Death (Against All Defendants)

☐ Count XXIII: Survival Action (Against All Defendants)

Furthermore, Plaintiff(s) assert(s) the following additional theories and/or State Causes of Action against Defendant(s) identified in Paragraph nine (9) above. If Plaintiff(s) includes additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pled by Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure.

**WHEREFORE**, Plaintiff(s) pray(s) for relief and judgment against Defendants of compensatory damages, punitive damages, interest, costs of suit, and such further relief as the Court deems equitable and just, and as set forth in the Master Long Form Complaint as appropriate.

**JURY DEMAND**

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

Respectfully Submitted by,

ONDERLAW, LLC

By: /s/ Stephanie L Rados
James G. Onder, #38049
William W. Blair, #58196
Stephanie L. Rados, #65117
110 E. Lockwood, 2nd Floor
St. Louis, MO 63119

314-963-9000 telephone
314-963-1700 facsimile
onder@onderlaw.com
blair@onderlaw.com
rados@onderlaw.com

**Counsel for Plaintiff(s)**

**CERTIFICATE OF SERVICE**

I hereby certify that on October 19, 2020, a copy of the foregoing FIRST AMENDED SHORT FORM COMPLAINT AND JURY DEMAND was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

/s/ Stephanie L. Rados

# EXHIBIT 4

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION** | **MDL NO. 16-2738 (FLW) (LHG)**<br>**JUDGE FREDA L. WOLFSON**<br>**MAG. JUDGE LOIS H. GOODMAN** |
| ANNA GALLARDO,<br><br>Plaintiff,<br><br>v.<br><br>JOHNSON & JOHNSON, INC., JOHNSON & JOHNSON CONSUMER, INC., AND IMERYS TALC AMERICA, INC. F/K/A LUZENAC AMERICA, INC.<br><br>Defendants. | COMPLAINT AND JURY DEMAND<br><br>Civil Action No.: 3:18-cv-10840<br><br>Case Management Order No. 8 Matter<br><br>Gallardo, et al. v. Johnson & Johnson, et al.<br><br>Docket Number: 4:17-cv-01601-FLW-LHG |

**SHORT FORM COMPLAINT AND JURY DEMAND**

The Plaintiff(s) named below file(s) this *Short Form Complaint and Demand for Jury Trial* against Defendants named below by and through the undersigned counsel. Plaintiff(s) incorporate(s) by reference the allegations contained in *Plaintiffs' Master Long Form Complaint* in *In re: Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation*, MDL No. 2738 in the United States District Court for the District of New Jersey. Plaintiff(s) file(s) this Short Form Complaint as permitted by Case Management Order No. 1 of this Court.

In addition to those causes of action contained in *Plaintiffs' Master Long Form Complaint*, where certain claims require specific pleadings and/or amendments, Plaintiff(s) shall add and include them herein.

## IDENTIFICATION OF PARTIES

**Identification of Plaintiff(s)**

1. Name of individual injured due to the use of talcum powder product(s): Anna Gallardo

2. At the time of the filing of the specific case, Plaintiff(s) is/are a citizen of St. Louis County, MO.

3. Consortium Claim(s): The following individual(s) allege damages for loss of consortium: _____.

4. Survival and/or Wrongful Death Claims:

   Name and residence of Decedent Plaintiff when she suffered the talcum powder product(s) related death: _____

   _____

5. Plaintiff/Decedent was born on _1952_ and died on _____.

6. Plaintiff is filing this case in a representative capacity as the_____ of the _____, having been duly appointed as the _____ _____ by the _____ Court of _____ _____.

7. As a result of using talcum powder products, Plaintiff/Decedent suffered personal and economic injur(ies) that are alleged to have been caused by the use of the products identified in Paragraph 16 below, but not limited to, the following:

   X_____ injury to herself

   _____ injury to the person represented

_____ wrongful death

_____ survivorship action

X____ economic loss

_____ loss of services

_____ loss of consortium

_____ other:_____

**Identification of Defendants**

8. Plaintiff(s)/Decedent Plaintiff(s) is/are suing the following Defendant(s) (please check all that apply)[1]

☒ Johnson & Johnson

☒ Johnson & Johnson Consumer Inc.

☒ Imerys Talc America, Inc. ("Imerys Talc")

☐ Personal Care Products Council ("PCPC")

**Additional Defendants:**

☐ Other(s) Defendant(s) (please specify):_____

**JURISDICTION & VENUE**

**Jurisdiction:**

9. Jurisdiction in this Short Form Complaint is based on:

☒ Diversity of Citizenship

[1] If additional Counts and/or Counts directed to other Defendants are alleged by the specific Plaintiff(s) as to whom this *Short Form Complaint* applies, the specific facts supporting these allegations must be pleaded by the Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure, and the Defendants against whom they are alleged must be specifically identified on a separate sheet of paper attached to this *Short Form Complaint*.

□ Other (The basis of any additional ground for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure).

**Venue:**

10. District Court(s) and Division (if any) in which venue was proper where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court and to where remand could be ordered by the Judicial Panel for trial: United States District Court for the Eastern District of Missouri.

## CASE SPECIFIC FACTS

11. Plaintiff(s) currently reside(s) in (City, State): _Clayton, MO.

12. At the time of the Plaintiff's/Decedent's diagnosis with a talcum powder product(s) injury, Plaintiff/Decedent resided in (City, State): Clayton, MO.

13. The Plaintiff/Decedent was diagnosed with a talcum powder product(s) injury in (City, State): _St. Louis, MO. on or about _July 2013.

14. To the best of Plaintiff's knowledge, Plaintiff/Decedent began using talcum powder product(s) on or about the following date: 1968 and continued the use of talcum powder product(s) through about the following date: 1988.

15. The Plaintiff/Decedent purchased talcum powder product(s) in the following State(s): _Missouri.

16. Plaintiff/Decedent used the following talcum powder products:

☒ Johnson & Johnson's Baby Powder

☐ Shower to Shower

## CAUSES OF ACTION

17. Plaintiff(s) hereby adopt(s) and incorporate(s) by reference the *Master Long Form Complaint and Jury Demand* as if fully set forth herein.

18. The following claims and allegations asserted in the *Master Long Form Complaint and Jury Demand* are herein adopted by reference by Plaintiff(s):

- ☒ Count I: Products Liability – Strict Liability – Failure to Warn (Against Imerys Talc)
- ☒ Count II: Products Liability – Strict Liability – Failure to Warn (Against the Johnson & Johnson Defendants)
- ☒ Count III: Products Liability – Strict Liability – Defective Manufacturer and Design (Against Imerys Talc)
- ☒ Count IV: Products Liability – Strict Liability – Defendant Manufacturer and Design (Against the Johnson & Johnson Defendants)
- ☒ Count V: Breach of Express Warranties (Against the Johnson & Johnson Defendants)
- ☒ Count VI: Breach of Implied Warranty of Merchantability (Against the Johnson & Johnson Defendants)
- ☒ Count VII: Breach of Implied Warranty of Fitness for a Particular Purpose (Against the Johnson & Johnson Defendants)
- ☒ Count VIII: Negligence (Against Imerys Talc)
- ☒ Count IX: Negligence (Against the Johnson & Johnson Defendants)
- ☐ Count X: Negligence (Against PCPC)
- ☒ Count XI: Negligent Misrepresentation (Against the Johnson & Johnson Defendants)

☒ Count XII: Fraud (Against the Johnson & Johnson Defendants)

☐ Count XIII: Fraud (Against PCPC)

☒ Count XIV: Violation of State Consumer Protection Laws of the State(s) of Missouri (Against the Johnson & Johnson Defendants)

☒ Count XV: Fraudulent Concealment (Against Imerys Talc)

☒ Count XVI: Fraudulent Concealment (Against the Johnson & Johnson Defendants)

☐ Count XVII: Fraudulent Concealment (Against PCPC)

☒ Count XVIII: Civil Conspiracy (Against All Defendants)

☐ Count XIX: Loss of Consortium (Against All Defendants)

☒ Count XX: Punitive Damages (Against All Defendants)

☒ Count XXI: Discovery Rule and Tolling (Against All Defendants)

☒ Count XXII: Wrongful Death (Against All Defendants)

☒ Count XXIII: Survival Action (Against All Defendants)

Furthermore, Plaintiff(s) assert(s) the following additional theories and/or State Causes of Action against Defendant(s) identified in Paragraph nine (9) above. If Plaintiff(s) includes additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pled by Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure.

**WHEREFORE**, Plaintiff(s) pray(s) for relief and judgment against Defendants of compensatory damages, punitive damages, interest, costs of suit, and such further relief as the Court deems equitable and just, and as set forth in the Master Long Form Complaint as appropriate.

**JURY DEMAND**

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

Respectfully Submitted by,

ONDERLAW, LLC

By: /s/ Stephanie L Rados
James G. Onder, #38049
William W. Blair, #58196
Stephanie L. Rados, #65117
110 E. Lockwood, 2nd Floor
St. Louis, MO 63119
314-963-9000 telephone
314-963-1700 facsimile
onder@onderlaw.com
blair@onderlaw.com
rados@onderlaw.com

**Counsel for Plaintiff(s)**

# EXHIBIT 5

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION** | **MDL NO.: 16-2738 (FLW)(LHG)**<br><br>**JUDGE FREDA L. WOLFSON**<br>**MAG. JUDGE LOIS H. GOODMAN** |
| **CARTER JUDKINS**<br><br>**PLAINTIFF,**<br><br>**v.**<br><br>**JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER INC.,**<br><br>**DEFENDANTS.** | **CIVIL ACTION**<br>**FILE NO.: 3:19-cv-12430**<br><br>**AMENDED SHORT FORM COMPLAINT** |

**AMENDED SHORT FORM COMPLAINT**
**AND JURY DEMAND**

The Plaintiff(s) named below file(s) this *Amended Short Form Complaint and Demand for Jury Trial* against Defendants named below by and through the undersigned counsel. Plaintiff(s) incorporate(s) by reference the allegations contained in *Plaintiffs' Master Long Form Complaint* in *In re: Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation*, MDL No. 2738 in the United States District Court for the District of New Jersey.

In addition to those causes of action contained in *Plaintiffs' Master Long Form Complaint*, where certain claims require specific pleadings and/or amendments, Plaintiff(s) shall add and include them herein.

## IDENTIFICATION OF PARTIES

**Identification of Plaintiff(s):**

1. Name of individual injured due to the use of talcum powder product(s): Carter Judkins
2. At the time of the filing of the specific case, Plaintiff(s) is/are a citizen of New Hampshire
3. Consortium Claim(s): The following individual(s) allege damages for loss of consortium: N/A
4. Survival and/or Wrongful Death Claims:

   Name and residence of Decedent Plaintiff when she suffered the talcum powder product(s) related death: N/A
5. Plaintiff/Decedent was born on [redacted] and died on N/A.
6. Plaintiff is filing this case in a representative capacity as the N/A of the _____ having been duly appointed as the _____ by the _____ Court of _____.
7. As a result of using talcum powder products, Plaintiff/Decedent suffered personal and economic injur(ies) that are alleged to have been caused by the

use of the products identified in Paragraph 16 below, but not limited to, the following:

✓ Injury to herself

__ Injury to the person represented

__ Wrongful death

__ Survivorship action

✓ Economic loss

__ Loss of services

__ Loss of consortium

__ Other: _____

**Identification of Defendants:**

8. Plaintiff(s)/Decedent Plaintiff(s) is/are suing the following Defendant(s) (please check all that apply) [1]:

☒ Johnson & Johnson
☒ Johnson & Johnson Consumer Inc.
☐ Imerys Talc America, Inc. ("Imerys Talc")
☐ Personal Care Products Council ("PCPC")

[1] If additional Counts and/or Counts directed to other Defendants are alleged by the specific Plaintiff(s) as to whom this *Short Form Complaint* applies, the specific facts supporting these allegations must be pleaded by the Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure, and the Defendants against whom they are alleged must be specifically identified on a separate sheet of paper attached to this *Short Form Complaint.*

**Additional Defendants:**

☐ Other(s) Defendant(s) (please specify):_____

_____

_____

## JURISDICTION & VENUE

**Jurisdiction**:

9. Jurisdiction in this Short Form Complaint is based on:

☒ Diversity of Citizenship

☐ Other (The basis of any additional ground for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure). _____

_____

**Venue:**

10. District Court(s) and Division (if any) in which venue was proper where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court and to where remand could be ordered by the Judicial Panel for trial: District of New Hampshire, Concord Division

## CASE SPECIFIC FACTS

11. Plaintiff(s) currently reside(s) in (City, State): Dover, NH

12. At the time of the Plaintiff's/Decedent's diagnosis with a talcum powder product(s) injury, Plaintiff/Decedent resided in (City/State): Dover, NH

13. The Plaintiff/Decedent was diagnosed with a talcum powder product(s) injury in (City/State): Lebanon, NH on December 30, 2016 (Date).

14. To the best of Plaintiff's knowledge, Plaintiff/Decedent began using talcum powder product(s) on or about the following dates: 1971 and continued the use of talcum powder product(s) through about the following date: 2003.

15. The Plaintiff/Decedent purchased talcum powder product(s) in the following (State(s)): New Hampshire .

16. Plaintiff/Decedent used the following talcum powder products:

☒ Johnson & Johnson's Baby Powder

☒ Shower to Shower

## CAUSES OF ACTION

17. Plaintiff(s) hereby adopt(s) and incorporate(s) by reference the *Master Long Form Complaint and Jury Demand* as if fully set forth herein.

18. The following claims and allegations asserted in the *Master Long Form Complaint and Jury Demand* are herein adopted by reference by Plaintiff(s):

☐ Count I: Products Liability – Strict Liability – Failure to Warn (Against Imerys Talc)

☒ Count II: Products Liability – Strict Liability – Failure to Warn (Against the Johnson & Johnson Defendants)

☐ Count III: Products Liability – Strict Liability – Defective Manufacturer and Design (Against Imerys Talc)

☒ Count IV: Products Liability – Strict Liability – Defective Manufacturer and Design (Against the Johnson & Johnson Defendants)

☒ Count V: Breach of Express Warranties (Against the Johnson & Johnson Defendants)

☒ Count VI: Breach of Implied Warranty of Merchantability (Against the Johnson & Johnson Defendants)

☒ Count VII: Breach of Implied Warranty of Fitness for a Particular Purpose (Against the Johnson & Johnson Defendants)

☐ Count VIII: Negligence (Against Imerys Talc)

☒ Count IX: Negligence (Against the Johnson & Johnson Defendants)

☐ Count X: Negligence (Against PCPC)

☒ Count XI: Negligent Misrepresentation (Against the Johnson & Johnson Defendants)

☒ Count XII: Fraud (Against the Johnson & Johnson Defendants)

☐ Count XIII: Fraud (Against PCPC)

☒ Count XIV: Violation of State Consumer Protection Laws of the State of New Hampshire (Against the Johnson & Johnson Defendants).

☐ Count XV: Fraudulent Concealment (Against Imerys Talc)

☒ Count XVI: Fraudulent Concealment (Against the Johnson & Johnson Defendants)

☐ Count XVII: Fraudulent Concealment (Against PCPC)

☒ Count XVIII: Civil Conspiracy (Against All Defendants)

☐ Count XIX: Loss of Consortium (Against All Defendants)

☒ Count XX: Punitive Damages (Against All Defendants)

☒ Count XXI: Discovery Rule and Tolling (Against All Defendants)

☐ Count XXII: Wrongful Death (Against All Defendants)

☐ Count XXIII: Survival Action (Against All Defendants)

☐ Furthermore, Plaintiff(s) assert(s) the following additional theories and/or State Cause of action against Defendant(s) identified in Paragraph nine (9) above. If Plaintiff(s) includes additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pled by Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure.

_____

_____

_____

WHEREFORE, Plaintiff(s) pray(s) for relief and judgment against Defendants of compensatory damages, punitive damages, interest, costs of suit, and such further relief as the Court deems equitable and just, and as set forth in the Master Long Form Complaint as appropriate.

## JURY DEMAND

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

This 19th day of October, 2020.

Respectfully submitted,

By: */s/ Henry G. Garrard, III*
Henry G. Garrard, III
hgarrard@bbga.com
Georgia Bar No. 286300
James B. Matthews, III
jmatthews@bbga.com
Georgia Bar No. 477559
Andrew J. Hill, III
ahill@bbga.com
Georgia Bar No. 353300
Josh B. Wages
jwages@bbga.com
Georgia Bar No. 730098
Sara Schramm
sschramm@bbga.com
Georgia Bar No. 141793
***Counsel for the Plaintiff(s)***

**BLASINGAME, BURCH, GARRARD & ASHLEY, P.C.**
440 College Avenue, Suite 320
P.O. Box 832
Athens, GA 30603
706-354-4000

**CERTIFICATE OF SERVICE**

I herby certify that on the 19th day of October, the above and foregoing document was filed electronically and is available for viewing through this Court's ECF system. A true and correct copy has been served upon all counsel of record via the Court's ECF system.

Respectfully submitted,

By: */s/ Henry G. Garrard, III*

Henry G. Garrard, III
hgarrard@bbga.com

**BLASINGAME, BURCH, GARRARD & ASHLEY, P.C.**
440 College Avenue, Suite 320
P.O. Box 832
Athens, GA 30603
706-354-4000

# EXHIBIT 6

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **IN RE JOHNSON & JOHNSON**<br><br>**TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION**<br><br>TAMARA NEWSOME and DANIEL FRANCOIS<br><br>Plaintiff(s),<br><br>v.<br>JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER INC., IMERYS TALC AMERICA, INC.<br>Defendants. | **MDL NO. 16-2738 (FLW) (LHG)**<br><br>**JUDGE FREDA L. WOLFSON**<br>**MAG. JUDGE LOIS H. GOODMAN**<br><br>AMENDED SHORT FORM COMPLAINT AND JURY DEMAND<br><br>Civil Action File No.: 3:18-cv-17146<br><br>DIRECT FILED ACTION |

**AMENDED SHORT FORM COMPLAINT AND JURY DEMAND**

The Plaintiff(s) named below file(s) this *Short Form Complaint and Demand for Jury Trial* against Defendants named below by and through the undersigned counsel. Plaintiff(s) incorporate(s) by reference the allegations contained in *Plaintiffs' Master Long Form Complaint* in *In re: Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation*, MDL No. 2738 in the United States District Court for the District of New Jersey. Plaintiff(s) file(s) this Short Form Complaint as permitted by Case Management Order No. 1 of this Court.

In addition to those causes of action contained in *Plaintiffs' Master Long Form Complaint*, where certain claims require specific pleadings and/or amendments, Plaintiff(s) shall add and include them herein.

## IDENTIFICATION OF PARTIES

**Identification of Plaintiff(s):**

1. Name of individual injured due to the use of talcum powder product(s):

   Tamara Newsome

2. At the time of the filing of the specific case, Plaintiff(s) is/are a citizen of

   Maryland

3. Consortium Claim(s): The following individual(s) allege damages for loss of consortium: Daniel Francois

4. Survival and/or Wrongful Death Claims:

   Name and residence of Decedent Plaintiff when she suffered the talcum powder product(s) related death: N/A

5. Plaintiff/Decedent was born on [redacted] and died on N/A.

6. Plaintiff is filing this case in a representative capacity as the N/A of the _____ having been duly appointed as the _____ by the Court of _____.

7. As a result of using talcum powder products, Plaintiff/Decedent suffered personal and economic injur(ies) that are alleged to have been caused by the use of the products identified in Paragraph 16 below, but not limited to, the following:

   - ✓ Injury to herself
   - __ Injury to the person represented
   - __ Wrongful death
   - __ Survivorship action
   - ✓ Economic loss

__ Loss of services

✓ Loss of consortium

__ Other: _____

**Identification of Defendants:**

8. Plaintiff(s)/Decedent Plaintiff(s) is/are suing the following Defendant(s) (please check all that apply) [1]:

☒ Johnson & Johnson

☒ Johnson & Johnson Consumer Inc.

☒ Imerys Talc America, Inc. ("Imerys Talc")

☐ Personal Care Products Council ("PCPC")

**Additional Defendants:**

☐ Other(s) Defendant(s) (please specify):_____

_____

_____

## JURISDICTION & VENUE

**Jurisdiction**:

9. Jurisdiction in this Short Form Complaint is based on:

☒ Diversity of Citizenship

[1] If additional Counts and/or Counts directed to other Defendants are alleged by the specific Plaintiff(s) as to whom this *Short Form Complaint* applies, the specific facts supporting these allegations must be pleaded by the Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure, and the Defendants against whom they are alleged must be specifically identified on a separate sheet of paper attached to this *Short Form Complaint.*

☐ Other (The basis of any additional ground for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure).

**Venue:**

10. District Court(s) and Division (if any) in which venue was proper where you might have otherwise filed this Short Form Complaint absent the direct filing Order entered by this Court and to where remand could be ordered by the Judicial Panel for trial:

District of Maryland, Southern Division

**CASE SPECIFIC FACTS**

11. Plaintiff(s) currently reside(s) in (City, State): Lanham, MD
12. At the time of the Plaintiff's/Decedent's diagnosis with a talcum powder product(s) injury, Plaintiff/Decedent resided in (City/State): Lanham, MD
13. The Plaintiff/Decedent was diagnosed with a talcum powder product(s) injury in (City/State): Silver Spring, MD on March 23, 2015 (Date).
14. To the best of Plaintiff's knowledge, Plaintiff/Decedent began using talcum powder product(s) on or about the following dates: 1975 and continued the use of talcum powder product(s) through about the following date: 2015.
15. The Plaintiff/Decedent purchased talcum powder product(s) in the following (State(s)): Maryland.
16. Plaintiff/Decedent used the following talcum powder products:

☒ Johnson & Johnson's Baby Powder

☐ Shower to Shower

**CAUSES OF ACTION**

17. Plaintiff(s) hereby adopt(s) and incorporate(s) by reference the *Master Long Form Complaint and Jury Demand* as if fully set forth herein.

18. The following claims and allegations asserted in the *Master Long Form Complaint and Jury Demand* are herein adopted by reference by Plaintiff(s):

☒ Count I: Products Liability – Strict Liability – Failure to Warn (Against Imerys Talc)

☒ Count II: Products Liability – Strict Liability – Failure to Warn (Against the Johnson & Johnson Defendants)

☒ Count III: Products Liability – Strict Liability – Defective Manufacturer and Design (Against Imerys Talc)

☒ Count IV: Products Liability – Strict Liability – Defective Manufacturer and Design (Against the Johnson & Johnson Defendants)

☒ Count V: Breach of Express Warranties (Against the Johnson & Johnson Defendants)

☒ Count VI: Breach of Implied Warranty of Merchantability (Against the Johnson & Johnson Defendants)

☒ Count VII: Breach of Implied Warranty of Fitness for a Particular Purpose (Against the Johnson & Johnson Defendants)

☒ Count VIII: Negligence (Against Imerys Talc)

☒ Count IX: Negligence (Against the Johnson & Johnson Defendants)

☐ Count X: Negligence (Against PCPC)

☒ Count XI: Negligent Misrepresentation (Against the Johnson & Johnson Defendants)

☒ Count XII: Fraud (Against the Johnson & Johnson Defendants)

☐ Count XIII: Fraud (Against PCPC)

☒ Count XIV: Violation of State Consumer Protection Laws of the State of Maryland (Against the Johnson & Johnson Defendants).

☒ Count XV: Fraudulent Concealment (Against Imerys Talc)

☒ Count XVI: Fraudulent Concealment (Against the Johnson & Johnson Defendants)

☐ Count XVII: Fraudulent Concealment (Against PCPC)

☒ Count XVIII: Civil Conspiracy (Against All Defendants)

☒ Count XIX: Loss of Consortium (Against All Defendants)

☒ Count XX: Punitive Damages (Against All Defendants)

☒ Count XXI: Discovery Rule and Tolling (Against All Defendants)

☐ Count XXII: Wrongful Death (Against All Defendants)

☐ Count XXIII: Survival Action (Against All Defendants)

☐ Furthermore, Plaintiff(s) assert(s) the following additional theories and/or State Cause of action against Defendant(s) identified in Paragraph nine (9) above. If Plaintiff(s) includes additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pled by Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure.

_____

_____

_____

WHEREFORE, Plaintiff(s) pray(s) for relief and judgment against Defendants of compensatory damages, punitive damages, interest, costs of suit, and such further relief as the Court deems equitable and just, and as set forth in the Master Long Form Complaint as appropriate.

**JURY DEMAND**

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

This 30th day of January, 2019.

Respectfully submitted,

By: */s/ Henry G. Garrard, III*

Henry G. Garrard, III
hgarrard@bbga.com
Georgia Bar No. 286300
James B. Matthews, III
jmatthews@bbga.com
Georgia Bar No. 477559
Andrew J. Hill, III
ahill@bbga.com
Georgia Bar No. 353300
Josh B. Wages
jwages@bbga.com
Georgia Bar No. 730098
Patrick H. Garrard
pgarrard@bbga.com
Georgia Bar No. 134007
***Counsel for the Plaintiff(s)***

BLASINGAME, BURCH,
GARRARD & ASHLEY, P.C.
440 College Avenue, Suite 320
P.O. Box 832
Athens, GA 30603
706-354-4000

# EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

| | | |
|---|---|---|
| PASQUALINA RAUSA, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | MDL NO. 16-2738 |
| vs. | ) | (FLW) (LHG) |
| | ) | |
| JOHNSON & JOHNSON, et al., | ) | CASE NO. |
| | ) | 3:20-cv-02947-FLW-LHG |
| Defendants. | ) | |

WEDNESDAY, JANUARY 27, 2021

Remote deposition of Pasqualina Rausa, conducted at the location of the witness in Ponte Vedra, Florida, commencing at 12:58 p.m., on the above date, before Dianne N. Sarkisian, Certified Shorthand Reporter and Registered Professional Reporter.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

education?
A. High school.
Q. Where did you go to high school?
A. Monsignor Scanlan High School in the Bronx, in New York.
Q. Were you born and raised in New York, in the Bronx?
A. Yes.
Q. And when did you leave New York?
A. I left New York in 2017.
Q. So from the time of your birth in 1955 until 2017, did you live in New York?
A. Yes.
Q. Did you live in the city that entire time?
A. I did not live in the city. I lived in a suburb. I lived in Rockland County. I mean, I lived in the Bronx when I was a single girl and then I moved to Queens after we got married and then to Rockland County. And then from Rockland, I came to Florida.
Q. Okay, great. So about what age were you when you moved to Queens, when you got married and moved to Queens?
A. 27.

MS. McGRODER: Object.
A. You want me to answer that?
BY MS. EMMEL:
Q. Yes, go ahead and answer.
A. They didn't show anything negative about it, so I took for granted it was.
Q. So when you saw them applying, um, when you saw the commercials where they were applying baby powder to babies, did that make you feel it was a safe product?
MS. McGRODER: Object to form, leading.
A. Yes.
BY MS. EMMEL:
Q. Did you ever see anything or hear anything prior to those advertisements in 2019 that indicated to you baby powder was unsafe?
A. No. The first time I heard that the baby powder was unsafe was when I heard the news program saying that there was litigation with Johnson & Johnson and they found asbestos in baby powder and it caused cancer.
Q. Did you ever see any warnings on the baby powder bottle --
A. No.
Q. -- indicating that baby powder may cause

# EXHIBIT 8

# Genital use of talc and risk of ovarian cancer: a meta-analysis

Wera Berge[a], Kenneth Mundt[b], Hung Luu[c] and Paolo Boffetta[d]

**Some epidemiological studies suggest an association between genital use of talc powders and increased risk of ovarian cancer, but the evidence is not consistent. We performed a meta-analysis of epidemiological studies to formally evaluate this suspected association. A systematic search was conducted in Medline, Embase, and Scopus, leading to the identification of 24 case–control studies and three cohort studies. In the meta-analysis, we used a random-effect model to calculate summary estimates of the association between genital use of talc and occurrence of ovarian cancer. We assessed potential sources of between-study heterogeneity and presence of publication bias. The summary relative risk (RR) for ever use of genital talc and ovarian cancer was 1.22 [95% confidence interval (CI): 1.13–1.30]. The RR for case–control studies was 1.26 (95% CI: 1.17–1.35) and for cohort studies was 1.02 (95% CI: 0.85–1.20, $P_{heterogeneity} = 0.007$). Serous carcinoma was the only histologic type for which an association was detected (RR: 1.24; 95% CI: 1.15–1.34). There was a weak trend in RR with duration and frequency of genital talc use. This meta-analysis resulted in a weak but statistically significant association between genital use of talc and ovarian cancer, which appears to be limited to serous carcinoma with suggestion of dose-response. The heterogeneity of results by study design however, detracts from a causal interpretation of this association.** *European Journal of Cancer Prevention* **27:248–257** 

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[a]Faculty of Medicine, University of Dresden, Dresden, Germany, [b]Ramboll Environ, Amherst, Massachusetts, [c]University of South Florida College of Public Health, Tampa, Florida and [d]Icahn School of Medicine at Mount Sinai, Tisch Cancer Institute, New York, New York, USA

Correspondence to Paolo Boffetta, MD, MPH, Icahn School of Medicine at Mount Sinai, Tisch Cancer Institute, One Gustave L. Levy Place, Box 1130, New York, NY 10029, USA
Tel: + 1 212 824 7378; fax: + 1 212 849 2566; e-mail: paolo.boffetta@mssm.edu

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## Introduction

With over 22 000 new cases diagnosed and about 14 000 deaths every year in the USA alone, ovarian cancer ranks as the fifth as a cause of neoplastic death among women. It accounts for more deaths than from any other cancer of the female reproductive system, although incidence numbers decreased since the mid-1980s (American Cancer Society, 2016). Most ovarian cancers are detected at a later stage and have limited prospects of cure. This is mainly because of the lack of a screening method for its detection at an early stage and resistance against chemotherapy. The etiology of the disease is not fully understood, although researchers have identified several risk factors, including a family history of ovarian or breast cancer, advanced age, white race, nulliparity, obesity, education level, and endometriosis (Kim *et al.*, 2014). In addition, breast feeding, tubal ligation, and oral contraceptive use have been reportedly associated with reduced risk (Webb *et al.*, 2008). Ovarian cancer is a heterogeneous disease that comprises four major histologic types; serous carcinoma is the most common form (50%), followed by mucinous, endometrioid, and clear cell carcinoma. Each type, with the exception of clear cell carcinoma, is divided into grades of malignancy (Wang *et al.*, 2005). On the basis of limited data, there appears to be some heterogeneity in risk factors for specific histologic types (Chiaffarino *et al.*, 2007; Gates *et al.*, 2010).

An association between exposure to asbestos and increased risk of ovarian cancer has been reported (Reid *et al.*, 2011), but it remains unclear whether this might reflect misclassification of peritoneal mesothelioma, a disease linked to high exposure to asbestos, or direct action of asbestos fibers on the ovary (Merino, 2010).

Talc is a naturally occurring mineral that is commonly used in bath and body powders as well as other cosmetic products. Talc naturally occurs as soft crystals that give it a soft, slippery feel, absorbency, softness, and resistance to clumping. It is often applied to sanitary napkins, condoms, or underwear, as well as directly to the genital area. To our knowledge, accurate estimates of prevalence of cosmetic talc use in the genital area are not available. However, the use of powders for female hygiene, including body or deodorizing powders containing cosmetic talc has been reported to be as high as 50% in some regions (International Agency for Research on Cancer (IARC), 2010), including parts of North America, Australia, and the UK.

Since 1982, when the first case–control study reported an association between genital talc and ovarian cancer, interest in genital talc use and risk of ovarian cancer has

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grown (Cramer *et al.*, 1982). The use of talcum powder in the genital area had been suggested as a potential risk factor for ovarian cancer based, in part, on a possible structural analogy with asbestos (Cramer *et al.*, 1982) or the possible contamination by asbestos of some talcum powders in the past (Cralley *et al.*, 1968). However, the structural similarities between asbestos minerals in the crystalline fiber form (i.e. asbestos habit) and structures seen microscopically in talcum that resemble fibers such as 'ribbons' of talc crystals or cleavage fragments of talc or other minerals, are few. Furthermore, talcum powders for domestic use in the USA have been virtually asbestos-free since the 1970s (Rohl *et al.*, 1976).

Several more recent case–control studies have reported associations between ovarian cancer and self-reported genital talcum powder use. However, the association between talc use and ovarian cancer risk reported in case–control studies has not been limited to studies in which genital talcum powder use occurred before cosmetic products were known to be asbestos-free. It has been suggested that talcum powder may be directly carcinogenic to the ovaries, provided that talc particles may be able to travel through the female reproductive system to the ovaries (Heller *et al.*, 1996). In one study, talc-like particles were detected more frequently in ovarian tumors than in normal human ovarian tissue, although the authors of this study emphasized that this study could not determine whether these particles actually caused the malignancy (Henderson *et al.*, 1979).

Results of epidemiological studies reported during the last three decades have not been consistent (Huncharek *et al.*, 2007; Terry *et al.*, 2013; Houghton *et al.*, 2014). It remains unclear whether a statistical association exists, and, if so, whether it can be interpreted as reflecting some form of bias or a causal relationship. We performed a systematic review and meta-analysis aiming at providing stronger evidence in favor or against the hypothesis of a causal association between genital talc use and risk of ovarian cancer.

## Methods

We performed a systematic review and meta-analysis on the association between genital talc powder use and the risk of ovarian cancer. Our work was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (Liberati *et al.*, 2009). A study protocol was developed in advance, outlining the procedure and methods (available upon request).

### Search strategy

A series of literature searches was conducted in June 2016 using the electronic databases Medline (by PubMed), Embase, and Scopus. There was no limitation on year of publication. We included relevant studies that met the following criteria: papers had to be published in peer-reviewed journals as an original report; had to present novel information on the relation between genital powder use and ovarian cancer, and had to be written in English, German, Italian, French or Spanish. As there are different types of genital powders, we defined genital powder as any type of powder that is applied to the genital, rectal or perineal area, such as talc, baby, deodorizing, cornstarch, or powder of unknown type. We excluded review articles, abstracts, editorials or letters to the editor not including original data, and other studies not meeting the selection criteria.

The following keywords were used for the searches on Medline and Scopus: 'perineal powder' or 'talcum powder' or 'genital powder' and 'ovarian cancer.' For Embase we used the following combination of keywords: 'perineum' or 'talc' and 'ovarian cancer.' In addition, all references cited in the identified papers and reviews were hand-searched for potentially relevant studies that were not captured by the electronic database search.

### Study selection

Titles and abstracts were examined independently by two of the authors (W.B., P.B.). Duplicates and irrelevant references were eliminated. In case of disagreement or doubt the abstracts or articles were discussed until consensus was reached. In case of overlap of results between publications the selection of results was on the basis of the largest population or most detailed analysis, resulting in the exclusion of some publications which were superseded by more recent reports (Harlow *et al.*, 1992; Cramer *et al.*, 1999; Pike *et al.*, 2004).

### Data extraction

All data of the included studies were extracted by one author (W.B.) and checked by another author (P.B.). Possible disagreements were discussed and solved.

The following data were extracted from each study for the meta-analysis: first author and publication year; study design; study region; period of enrollment; survey instrument; assessment of ovarian cancer; age range; numbers of women with ovarian cancer and those without in case–control studies; numbers of cases of ovarian cancer, sample size and a number of person-years in cohort studies; adjustment for potential confounding factors; outcome by talc exposure (yes/no); duration (years); frequency (times/week); timing of use (early/late); type of talc exposure (sanitary napkin, diaphragm, genital deodorant, cornstarch, use by the partner); endometriosis; surgery (hysterectomy and/or tubal ligation); number of powder applications; characteristics of the participants; and tumor histology and behavior.

### Quality assessment

Every included article was scored for its quality according to a standardized checklist. We used the Newcastle–Ottawa Scale (NOS) case–control checklist and the NOS cohort study checklist for both study types, respectively (Stang,

2010). The NOS assesses three dimensions of quality: selection, comparability, and exposure (for a case–control study) or outcome (for a cohort study). It assigns a maximum of four points for selection, two points for comparability, and three points for exposure or outcome. Studies with at least seven points were considered of high quality (Supplementary Table 1, Supplemental digital content 1, *http://links.lww.com/EJCP/A138* and Table 2, Supplemental digital content 2, *http://links.lww.com/EJCP/A139*).

### Statistical analyses

The measure of association of interest was the relative risk (RR) for prospective cohort studies, and the odds ratio (OR) for the case–control studies, with corresponding 95% confidence intervals (CIs). The main meta-analysis compared ever versus never use of genital talc; additional analyses addressed use of powder on sanitary napkins and diaphragms, two potential sources of talc exposure. If results were reported only by categories of exposure, indicators of ever talc use were derived using fixed-effect meta-analyses. Risk estimates were abstracted from each study for comparable exposure categories. An overall pooled RR was then estimated, together with its 95% CI, on the basis of individual estimates from each study. Each study was given a weight on the basis of the inverse of the variance of the effect estimate. We pooled data on different exposures when at least four studies provided sufficient data. A random-effects model was used in the meta-analyses comprising multiple studies, because of the heterogeneity in study design and analysis (DerSimonian and Laird, 1986). The $I^2$-statistic was used to assess the percentage of between-study variability that is because of heterogeneity rather than chance (Higgins *et al.*, 2003).

Stratified meta-analyses were conducted for ever genital use of talc according to study design (case–control vs. cohort studies), as well as tumor histology and behavior. Because of the fact that cosmetic talc may have been contaminated by asbestos before the 1970s, when voluntary guidelines were adopted, we compared the results on use in an 'early' and in a 'late' period: the exact cut-point varied across the studies but in general referred to 1970 or 1980.

Meta-regression analyses were performed to obtain overall risk estimates for duration (RR for 10-year increase in duration) and frequency of genital talc use (RR for one time/week increase in frequency), for the studies reporting at least three categories of duration or frequency of use. Study-specific slopes were first derived from the natural logarithm of the risk estimates within each study; in a second step the slopes were pooled using a random-effects model.

The presence and extent of publication bias were assessed visually using funnel plots and evaluated statistically using the Egger's test (Egger *et al.*, 1997). A cumulative meta-analysis was also performed by repeating the calculation of the summary RR and CI (on the basis of a random-effects model) each year a new study was published. When an article superseded a previous article from the same study, the results reported in the earlier report were replaced by the new results.

Analyses were performed using the commands *metan*, *glst*, *metafunnel*, and *metabias* of the statistical software STATA, version 14 (StataCorp, 2015).

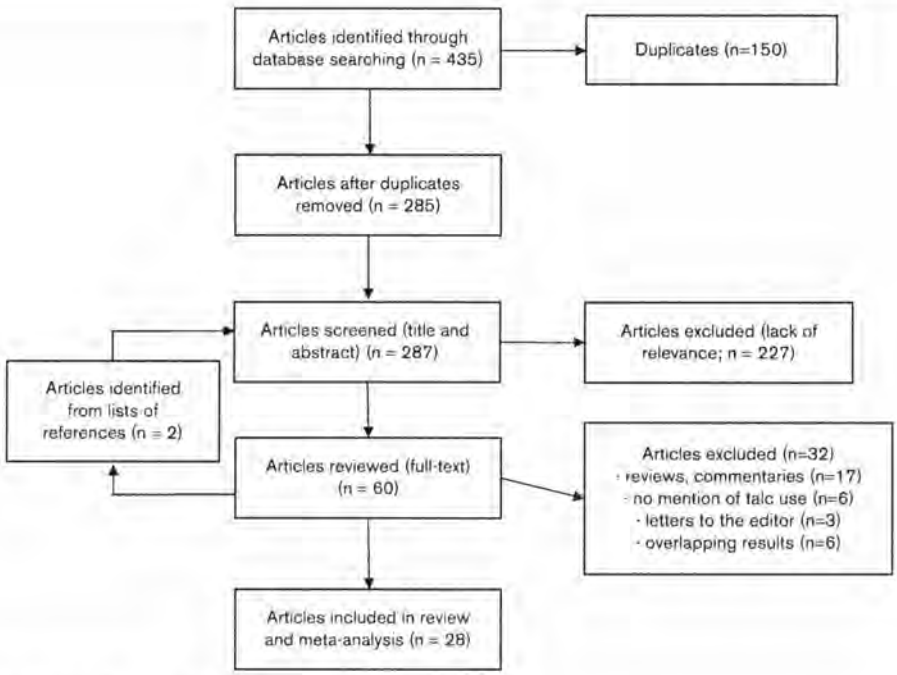
## Results

The process of selection of relevant studies is shown in Fig. 1. The electronic searches resulted in a total of 435 articles, of which 150 overlapped between searches. After the exclusion of the duplicates and the addition of two articles identified through the review of the lists of references of eligible articles, we screened the titles of abstracts of 287 articles, and excluded 227 which appeared not to be relevant. We then reviewed the full text of the remaining 60 articles, and excluded 32 (17 commentaries, reviews or meta-analysis; three letters to the editor without original results, six reports of studies of ovarian cancer without results on talc use, and six articles whose results were superseded by subsequent publications). The remaining 28 articles, comprising three cohort studies, 24 case–control studies, and one pooled analysis of eight of the 24 case–control studies, were included in the review and meta-analysis.

Table 1 shows selected characteristics of the 28 articles included in the review, which provided the 27 risk estimates included in the meta-analysis [the pooled analysis (Terry *et al.*, 2013) did not provide an independent risk estimate]. For three of the case–control studies included in the pooled analysis (Goodman *et al.*, 2008; Moorman *et al.*, 2009; Lo-Ciganic *et al.*, 2012) results on genital talc use had not been reported in the original publications and were abstracted from the pooled analysis (Terry *et al.*, 2013). Twenty studies were conducted in the USA, two in Australia, two in Canada, one in Great Britain, one in China, and one in Greece. Potential confounding factors including age, parity, history of tubal ligation or hysterectomy, and use of oral contraceptive were adjusted for in most studies, although there were differences in the specific adjustments across studies. Six of the 24 case–control studies were hospital-based with the remainder being population-based.

The results of the meta-analysis are reported in Table 2. We used the results reported in the meta-analysis by Terry *et al.* (2013) for six of the original eight studies (Chang and Risch, 1997; Goodman *et al.*, 2008; Merritt *et al.*, 2008; Moorman *et al.*, 2009; Rosenblatt *et al.*, 2011; Lo-Ciganic *et al.*, 2012), while for the remaining two studies (Cramer *et al.*, 1999; Pike *et al.*, 2004) we used the more extensive results reported in subsequent publications (Wu *et al.*, 2015; Cramer *et al.*, 2016).

**Fig. 1**




Flow chart for the selection of studies to include in the meta-analysis.

The meta-analysis of all 27 risk estimates for ever use of genital talc yielded a summary RR of 1.22 (95% CI: 1.13–1.30). The forest plot of these results is shown in Fig. 2. When the meta-analysis was stratified according to study design, an association with ever genital talc use was detected in case–control studies (RR: 1.26; 95% CI: 1.17–1.35), but not in cohort studies (RR: 1.02; 95% CI: 0.85–1.20). The *P*-value of the test for heterogeneity of results according to study design was 0.007. Furthermore, hospital-based case–control studies resulted in a higher summary RR than community-based case–control studies ($P = 0.3$, for heterogeneity between the two groups of case–control studies).

The meta-analysis stratified by tumor behavior did not reveal a difference between results for borderline (RR: 1.27; 95% CI: 1.09–1.44) and invasive ovarian cancer (RR: 1.20; 95% CI: 1.08–1.31). The analysis stratified by histology, however, identified an association between ever genital use of talc and serous carcinoma (RR: 1.24; 95% CI: 1.15–1.34, on the basis of 13 case–control studies and no cohort studies). No significant associations were detected for endometrial (RR: 1.15; 95% CI: 0.91–1.39), mucinous (RR: 0.96; 95% CI: 0.73–1.18) or clear cell (RR: 0.98; 95% CI: 0.72–1.23) carcinomas. The *P*-value of the test of heterogeneity between histologic types was 0.04. Only two cohort studies reported histology-specific results, showing neither a difference between types nor stronger association for serous carcinoma (results not shown in detail). Three of the studies (Mills *et al.*, 2004; Rosenblatt *et al.*, 2011; Cramer *et al.*, 2016) reported results for serous carcinoma stratified by tumor behavior: they did not suggest any difference (RR = 1.39, for borderline serous carcinoma; 95% CI: 1.04–1.74; RR: 1.32, for invasive serous carcinoma; 95% CI: 0.97–1.67; $P_{\text{heterogeneity}} = 0.5$).

Use of talcum powder in the 'early' period showed weakly increased risk of ovarian cancer (RR: 1.18; 95% CI: 0.99–1.37), whereas the RR for use in the 'late' period was slightly higher but less precisely estimated (RR: 1.31; 95% CI: 1.03–1.61). The *P*-value of the test for heterogeneity between groups of studies was 0.37.

Use of sanitary napkins or diaphragms was not associated with an increased risk of ovarian cancer (RR: 1.00; 95% CI: 0.84–1.16; and RR: 0.75; 95% CI: 0.63–0.88, respectively).

We conducted additional analyses after stratifying the studies according to whether the results were adjusted for key potential confounders (use of oral contraceptives and hormone replacement therapy, socioeconomic status/education, BMI; see Table 1 for details), but found no evidence of heterogeneity (results not shown in detail).

The results of the analysis by duration and frequency of genital talc use are reported in Table 3. A 10-year increase in genital talc use was associated with a RR of 1.16 (95% CI 1.07-1.26; 12 studies), whereas the RR for

**Table 1 Selected characteristics of the studies included in the meta-analysis**

| References | Country | Study type | Age range | N ca/co | Potential confounders | Inclusion in meta-analyses | Overlap between publications |
|---|---|---|---|---|---|---|---|
| Cramer *et al.* (1982) | USA | CCC | 18–80 | 215/215 | Pa, MS | E, N, D | |
| Hartge *et al.* (1983) | USA | HCC | NA | 135/171 | – | E, D | |
| Whittemore *et al.* (1988) | USA | HCC | 18–74 | 188/539 | Pa, OC | E, N, D, Du, F | |
| Booth *et al.* (1989) | UK | HCC | 20–64 | 235/451 | SES | E, F | |
| Harlow and Weiss (1989) | USA | CCC | 20–79 | 116/158 | Pa, OC | E, N, D | |
| Chen *et al.* (1992) | China | CCC | NA | 112/224 | Pa, Ed | E | |
| Harlow *et al.* (1992) | USA | CCC | 18–76 | 235/239 | Pa, Ed, MS, BMI | E, H, B, F, Du, T, N, D | |
| Rosenblatt *et al.* (1992) | USA | HCC | All | 77/46 | – | E, N, D | |
| Tzonou *et al.* (1993) | Greece | HCC | < 75 | 189/200 | Pa, Ed, BMI, AMe, MS, AFB, Tob, Cof, Alc, Med, HD | E | |
| Purdie *et al.* (1995) | Australia | CCC | 18–79 | 824/860 | Pa | E | |
| Chang and Risch (1997) | Canada | CCC | 35–79 | 450/564 | OC, NPr, BF, TL, Hys, FH | Du, T, N | Included in Terry *et al.* (2013) |
| Cook *et al.* (1997) | USA | CCC | 20–79 | 313/422 | – | E, H, Du, N, D | |
| Godard *et al.* (1998) | Canada | CCC | 20–84 | 170/170 | – | E | |
| Wong *et al.* (1999) | USA | HCC | NA | 499/755 | Pa, OC, Tob, FH, AMe, MS, Inc, Ed, TL, Hys | E, Du, N | |
| Ness *et al.* (2000) | USA | CCC | 20–69 | 767/1367 | NPr, FH, OC, TL, Hys, BF | E, Du, N, D | |
| Mills *et al.* (2004) | USA | CCC | 18+ | 256/1122 | OC, BF | E, H, B, F, Du, T | |
| Goodman *et al.* (2008) | USA | CCC | 18+ | 367/602 | NA | | Included in Terry *et al.* (2013) |
| Merritt *et al.* (2008) | Australia | CCC | 18–79 | 1576/1509 | Pa, Ed, OC | Du | Included in Terry *et al.* (2013) |
| Moorman *et al.* (2009) | USA | CCC | 20–74 | 1086/1057 | – | | Included in Terry *et al.* (2013) |
| Gates *et al.* (2010) | USA | Cohort | 30–55 | 721/– | Pa, BMI, PA, Tob, FH, BF, OC, TL, Hys, Amp, HRT | E, H, F[a], N[a] | |
| Rosenblatt *et al.* (2011) | USA | CCC | 35–74 | 812/1313 | NPr, OC | Du, T, N, D | Included in Terry *et al.* (2013) |
| Lo-Ciganic *et al.* (2012) | USA | CCC | 25+ | 902/1802 | NA | | Included in Terry *et al.* (2013) |
| Terry *et al.* (2013) | USA, Canada, Australia | | | | Pa, OC, TL, BMI | E, H, B | Pooled data from Chang and Risch (1997), Goodman *et al.* (2008), Moorman *et al.* (2009), Rosenblatt *et al.* (2011), Lo-Ciganic *et al.* (2012), Merritt *et al.* (2008) |
| Houghton *et al.* (2014) | USA | Cohort | 50–79 | 429/– | Pa, OC, HRT, FH, ALB, BMI, Tob, TL | E, H, N, D, DU | |
| Wu *et al.* (2015) | USA | CCC | 18–74 | 1701/2391 | MS, AMe, HRT, BMI, Inc, Ed, NPr, OC, TL, End, FH | E, T[b] | |
| Cramer *et al.* (2016) | USA | CCC | 18–80 | 2041/2100 | – | E, H, B, F, Du, D | |
| Gonzalez *et al.* (2016) | USA, Puerto Rico | Cohort | 35–74 | 154/– | BMI, OC, MS, TL, Hys | E | |
| Schildkraut *et al.* (2016) | USA | CCC | 20–79 | 584/745 | Pa, Ed, OC, BMI, TL, FH | E, H, Du, F | |

N ca/co, number of cases and controls (only cases for cohort studies).
AFB, age at first birth; ALB, age at last birth; AMe, age at menarche; AMp, age at menopause; B, tumor behavior; BF, breast feeding; CCC, community-based case–control study; D, diaphragm use; Du, duration of use; E, ever use; Ed, education; F, frequency of use; FH, family history of breast and ovarian cancer; H, histologic type; HCC, hospital-based case–control study; HD, hair dye use; HRT, hormone replacement therapy; Hys, hysterectomy; Inc, income; Med, use of medications; MS, menopausal status; N, sanitary napkin use; NA, not available; NPr, number of pregnancies; OC, oral contraceptive use; Pa, parity; SES, socioeconomic status; T, timing of use; TL, tubal ligation.
[a]Results abstracted from Gertig *et al.* (2000).
[b]Results abstracted Wu *et al.* (2009).

**Table 2 Ever use of genital talc – results of meta-analysis**

| | Number of risk estimates | RR | 95% CI | p-het |
|---|---|---|---|---|
| Overall | 27 | 1.22 | 1.13–1.30 | 0.02 |
| Study design | | | | |
| Cohort studies | 3 | 1.02 | 0.85–1.20 | 0.2 |
| Case–control studies | 24 | 1.26 | 1.17–1.35 | 0.08 |
| Hospital-based case–control studies | 6 | 1.34 | 1.16–1.51 | 0.8 |
| Community-based case–control studies | 18 | 1.24 | 1.13–1.35 | 0.03 |
| Histology | | | | |
| Serous carcinoma | 13 | 1.24 | 1.15–1.34 | 0.4 |
| Mucinous carcinoma | 12 | 0.96 | 0.73–1.18 | 0.8 |
| Endometrial carcinoma | 12 | 1.15 | 0.91–1.39 | 0.1 |
| Clear cell carcinoma | 8 | 0.98 | 0.72–1.23 | 0.8 |
| Behavior | | | | |
| Invasive | 9 | 1.20 | 1.08–1.31 | 0.2 |
| Borderline | 9 | 1.27 | 1.09–1.44 | 0.9 |
| Period of exposure[a] | | | | |
| Early | 5 | 1.18 | 0.99–1.37 | 0.2 |
| Late | 5 | 1.31 | 1.03–1.61 | 0.2 |
| Specific sources of talc exposure | | | | |
| Sanitary napkin | 12 | 1.00 | 0.84–1.16 | 0.5 |
| Diaphragm | 11 | 0.75 | 0.63–0.88 | 0.8 |

CI, confidence interval; p-het, *P*-value of test for interstudy heterogeneity; RR, relative risk.
[a]Cut-points between periods vary across studies but in general refer to 1970 or 1980.

an increase of one application per week was 1.05 (95% CI 1.04-1.07; 7 studies).

The funnel plot of the results of ever genital talc use is shown in Fig. 3. Visual inspection of the plot suggests no serious publication bias: this conclusion is supported by the result of the Egger test ($P=0.7$). The results of the cumulative meta-analysis (Fig. 4) suggest that after the publication of a few initial studies with inconsistent results, the summary RR stabilized with values in the range of 1.20–1.25.

## Discussion

Ovarian cancer, unless diagnosed and treated early, remains a highly lethal disease and the identification of modifiable risk factors is an important component of the strategy for its control. The primary aim of this meta-analysis was to determine whether talcum powder use in the female genital area is a potential risk factor for ovarian cancer. Previous meta-analyses (Huncharek *et al.*, 2003; Langseth *et al.*, 2008) were only on the basis of a fraction of currently available studies, and had limited ability to explore potential sources of heterogeneity in results.

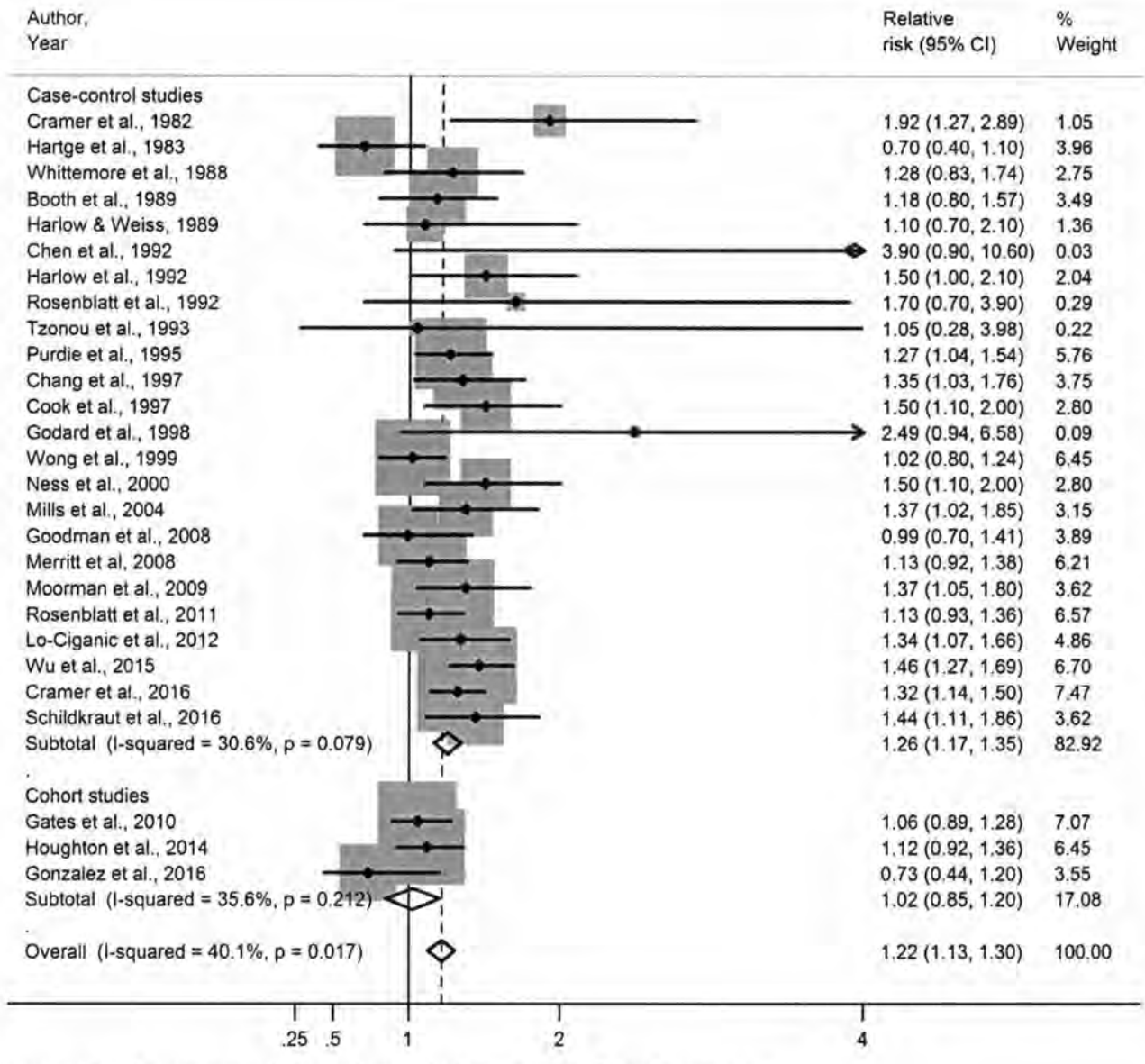
This meta-analysis suggests that genital powder use is associated with a small increased risk of developing ovarian cancer; however, this positive association appears to be limited to the serous histologic type, and to case–control studies. This estimate is somewhat lower than that of previous meta-analyses (Huncharek *et al.*, 2003; Langseth *et al.*, 2008): in our cumulative meta-analysis we confirmed the trend toward lower overall risk estimates as more evidence accumulated.

An important feature of the present meta-analysis is the inclusion of several cohort studies, which enabled an analysis stratified by study design. This analysis provided evidence of heterogeneity of results between the two groups of studies, with an association generally detected in case–control studies but not in cohort studies. It should be noted that the cohort studies included in the meta-analysis comprised a total of 429 cases of ovarian cases exposed to genital talc and 943 unexposed cases: the statistical power of the meta-analysis of these cohort studies to detect a RR of 1.25, similar to the result of the meta-analysis of case–control studies, was 0.99. Thus, low power of cohort studies cannot be invoked as explanation of the heterogeneity of results.

The fact that the association between genital talc use and risk of ovarian cancer is present in case–control, but not in cohort studies, can be attributed to bias in the former type of studies (Kopec and Esdaile, 1990; Rothman *et al.*, 2008). Selection bias might have played a role in the results of some of the case–control studies (e.g. those with low response rate, or those hospital-based, which resulted in a nonsignificantly higher summary risk estimate than community-based studies); in addition, information bias from retrospective self-report of talc use is a possible explanation for the association detected in case–control studies. In particular, some of the most recent case–control studies (Cramer *et al.*, 2016; Schildkraut *et al.*, 2016) have reported particularly strong associations (RR >1.4) for ever use of talc. These results may have occurred at least in part because of participants' knowledge about the latest controversies about talc use and ovarian cancer risk spread by the media (Muscat and Huncharek, 2008).

The results of the analysis by histologic type of ovarian cancer pointed toward an association with serous carcinoma, but not with the other main types (i.e. endometrial, mucinous, and clear cell carcinoma). Several studies have suggested heterogeneity in risk factors of different histologic types, which are characterized by distinctive molecular and genetic profiles (Kurian *et al.*, 2005; Gates *et al.*, 2010; Gilks, 2010). However, no results are available on whether the association between asbestos exposure and ovarian cancer risk varies by histologic type (Camargo *et al.*, 2011; Reid *et al.*, 2011). The finding that the association between genital talc use and ovarian cancer may vary by histologic type detracts from the hypothesis of report bias as an explanation of the findings of case–control studies, as this type of bias would likely operate for all histologic types of the disease. Caution should however be warranted in the interpretation of these findings, as the test for heterogeneity between groups was of borderline statistical significance, and the evidence for heterogeneity derives only from case–control studies.

Fig. 2




Forest plot of results on ever use of genital talc and risk of ovarian cancer. CI, confidence interval.

**Table 3 Duration and frequency of use of genital talc – results of meta-analysis**

| | Number of risk estimates | RR | 95% CI |
|---|---|---|---|
| Duration (10 years) | 12 | 1.16 | 1.07–1.26 |
| Frequency (1 time/week) | 7 | 1.05 | 1.04–1.07 |

CI, confidence interval; p-het, RR, relative risk.

The presence or absence of a dose–response is an important aspect to consider in assessing the plausibility of the causal nature of an association observed in a meta-analysis. The number of studies included in the analysis of duration and frequency of genital talc use was not very large, and the modest association between both duration and frequency of use of talc may reflect a true relationship, or recall bias or confounding, and analyses based on larger datasets would be required is a potentially important and novel contribution of this meta-analysis.

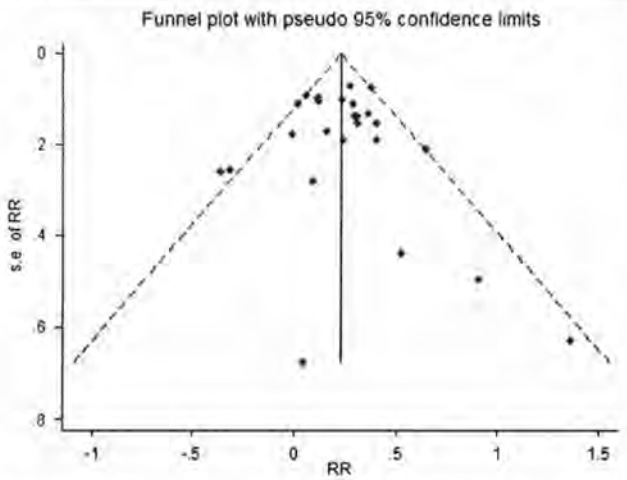
We aimed at analyzing the results on genital use of talc according to time-periods; this analysis was limited by different cut-points used by various authors to define time intervals of exposure. In general, however, we were able to distinguish an 'early' and a 'late' period, with the limit between the two running between 1970 and 1980, and we found a statistically significant association only for 'late' use. This result goes against the hypothesis that a stronger association (if any) would be seen among those

more likely to have used talcum powders in a time period in which contamination with asbestos fibers was possible (Rohl *et al.*, 1976).

Our study suffers from limitations common to meta-analyses of observational studies: neither the definition of the exposure of interest (genital talc use) nor the strategy for adjustment for potential confounders were fully consistent across studies. Also, there were limitations not specific to our study, including the self-reported information on the main exposure of interest, with no external validation data, the predominance of retrospective case–control studies, and the small number of studies providing results by histologic type or quantitative measures of genital talc use. It is difficult to assess the combined effect of the potential sources of bias, as they might have operated in different directions on the estimate of the association between talc use and ovarian cancer. The stratified analyses we conducted did not point toward the presence of residual confounding (i.e. higher risk estimates for unadjusted compared with adjusted results).

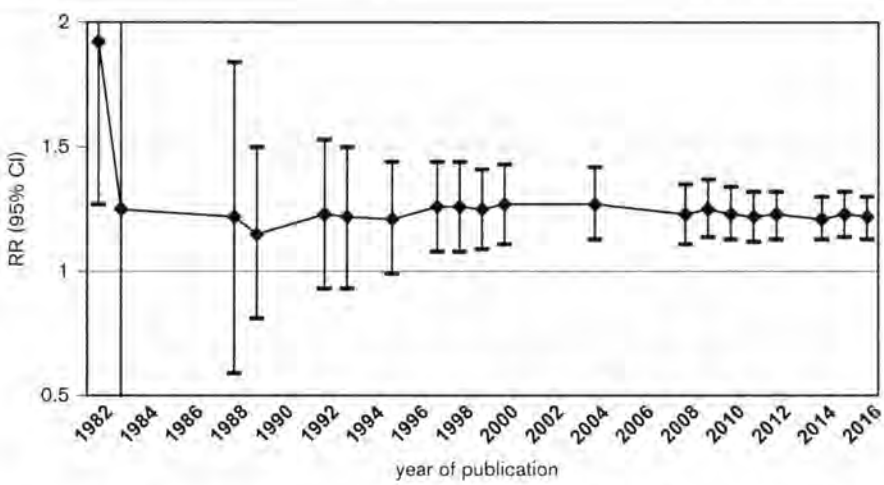
The biological basis and plausibility of a possible carcinogenic effect of talc on the ovaries is still not understood and remains questionable. The similarity of physicochemical characteristics of talc and asbestos has been proposed to explain a carcinogenic effect of the former (Cramer *et al.*, 1982). However, although both talc and various forms of asbestos minerals belong to the family of silicates, they are morphologically distinct. It is the fibrous form of asbestos which determines its carcinogenic potential (Stanton *et al.*, 1981; Huncharek, 1986; Mossman and Gee, 1989). Talc is not fibrous or crystalline (International Agency for Research on Cancer (IARC), 2010), and in-vitro studies have shown that talc is not genotoxic (Wehner, 1994). This is supported by the evidence that exposure to talc not contaminated with asbestiform fibers is not associated with increased risk of lung cancer or mesothelioma in occupational cohorts (International Agency for Research on Cancer (IARC), 2010). The occupational cohorts supporting this conclusion comprise mostly men, and therefore provide no evidence in favor or against the hypothesis of a role of occupational talc exposure as an ovarian carcinogen, but the likelihood that talc could selectively cause ovarian cancer but not lung cancer or mesothelioma at high concentrations in talc miners and millers appears to be low. Furthermore, there is no evidence that occupational exposure to talc, for example, in the pulp and paper

**Fig. 3**




Funnel plot of results on ever use of genital talc and risk of ovarian cancer. RR, relative risk.

**Fig. 4**




Cumulative meta-analysis of results on ever use of genital talc and risk of ovarian cancer. CI, confidence interval; RR, relative risk.

industry, entails an increased risk of ovarian cancer (Langseth and Kjaerheim, 2004).

In conclusion, our meta-analysis identified a small but statistically significant association between genital talc use and risk of ovarian cancer; however, this association was limited to the serous histologic type, and to case–control studies. The results by histologic type might argue for specificity of the association, in the absence, however, of a biologic rationale for an effect on serous carcinoma compared with other types. Several aspects of our results, including the heterogeneity of results between case–control and cohort studies, however, do not support a causal interpretation of the association.

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### Conflicts of interest

There are no conflicts of interest.

## References

American Cancer Society (2016). *Cancer facts and figures 2016*. Atlanta, GA: American Cancer Society.

Booth M, Beral V, Smith P (1989). Risk factors for ovarian cancer: a case–control study. *Br J Cancer* **60**:592–598.

Camargo MC, Stayner LT, Straif K, Reina M, Al-Alem U, Demers PA, *et al.* (2011). Occupational exposure to asbestos and ovarian cancer: a meta-analysis. *Environ Health Perspect* **119**:1211–1217.

Chang S, Risch HA (1997). Perineal talc exposure and risk of ovarian carcinoma. *Cancer* **79**:2396–2401.

Chen Y, Wu PC, Lang JH, Ge WJ, Hartge P, Brinton LA (1992). Risk factors for epithelial ovarian cancer in Beijing, China. *Int J Epidemiol* **21**:23–29.

Chiaffarino F, Parazzini F, Bosetti C, Franceschi S, Talamini R, *et al.* (2007). Risk factors for ovarian cancer histotypes. *Eur J Cancer* **43**:1208–1213.

Cook LS, Kamb ML, Weiss NS (1997). Perineal powder exposure and the risk of ovarian cancer. *Am J Epidemiol* **145**:459–465.

Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo RM (1968). Fibrous and mineral content of cosmetic talcum products. *Am Ind Hyg Assoc J* **29**:350–354.

Cramer DW, Welch WR, Scully RE (1982). Ovarian cancer and talc: a case control study. *Cancer* **50**:372–376.

Cramer DW, Liberman RF, Titus-Ernstoff L, Welch WR, Greenberg ER, Baron JA, *et al.* (1999). Genital talc exposure and risk of ovarian cancer. *Int J Cancer* **81**:351–356.

Cramer DW, Vitonis AF, Terry KL, Welch WR, Titus LJ (2016). The association between talc use and ovarian cancer. A retrospective case–control study in two US states. *Epidemiol* **27**:334–346.

DerSimonian R, Laird N (1986). Meta-analysis in clinical trials. *Control Clin Trials* **7**:177–188.

Egger M, Smith GD, Schneider M, Minder C (1997). Bias in meta-analysis detected by a simple, graphical test. *BMJ* **315**:629–634.

Gates MA, Rosner BA, Hecht JL, Tworoger SS (2010). Risk factors for epithelial ovarian cancer by histologic type. *Am J Epidemiol* **171**:45–53.

Gertig DM, Hunter DJ, Cramer DW, Colditz GA, Speizer FE, Willett EC, *et al.* (2000). Prospective study of talc use and ovarian cancer. *J Natl Cancer Inst* **92**:249–252.

Gilks CB (2010). Molecular abnormalities in ovarian cancer subtypes other than high-grade serous carcinoma. *J Oncol* **2010**:740968.

Godard B, Foulkes WD, Provencher D, Brunet JS, Tonin PN, Mes-Masson AM, *et al.* (1998). Risk factors for familial and sporadic ovarian cancer among French Canadians: a case–control study. *Am J Obstet Gynecol* **179**:403–410.

Gonzalez NL, O'Brien KM, D'Aloisio AA, Sandler DP, Weinberg CR (2016). Douching, talc use and risk of ovarian cancer. *Epidemiol* **27**:797–802.

Goodman MT, Lurie G, Thompson PJ, McDuffie KE, Carney ME (2008). Association of two common single-nucleotide polymorphisms in the CYP19A1 locus and ovarian cancer risk. *Endocr Relat Cancer* **15**:1055–1060.

Harlow BL, Weiss NS (1989). A case–control study of borderline ovarian tumors: the influence of perineal exposure to talc. *Am J Epidemiol* **130**:390–394.

Harlow BL, Cramer DW, Bell DA, Welch WR (1992). Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol* **80**:19–26.

Hartge P, Hoover R, Lesher LP, McGowan L (1983). Talc and ovarian cancer. *JAMA* **250**:1844.

Heller DS, Westhoff C, Gordon RE, Katz N (1996). The relationship between perineal cosmetic talc usage and ovarian talc particle burden. *Am J Obstet Gynecol* **174**:1507–1510.

Henderson WJ, Hamilton TC, Griffiths K (1979). Talc in normal and malignant ovarian tissue. *Lancet* **1**:499.

Higgins JPT, Thompson SG, Deeks JJ, Altman DG (2003). Measuring inconsistency in meta-analyses. *BMJ* **327**:557–560.

Houghton SC, Reeves KW, Hankinson SE, Crawford L, Lane D, Wactawski-Wende J, *et al.* (2014). Perineal powder use and risk of ovarian cancer. *J Natl Cancer Inst* 106dju208.

Huncharek M (1986). The biomedical and epidemiological characteristics of asbestos-related diseases: a review. *Yale J Biol Med* **59**:435–451.

Huncharek M, Geschwind JF, Kupelnick B (2003). Perineal application of cosmetic talc and risk of invasive epithelial ovarian cancer: a meta-analysis of 11 933 subjects from sixteen observational studies. *Anticancer Res* **23**:1955–1960.

Huncharek M, Muscat J, Onitilo A, Kupelnick B (2007). Use of cosmetic talc on contraceptive diaphragms and risk of ovarian cancer: a meta-analysis of nine observational studies. *Eur J Cancer Prev* **16**:422–429.

International Agency for Research on Cancer (IARC). (2010). Talc not containing asbestiform fibres. *IARC monographs on the evaluation of carcinogenic risks to humans*. Lyon, France: IARC. pp. 277–413.

Kim HS, Kim TH, Chung HH, Song YS (2014). Risk and prognosis of ovarian cancer in women with endometriosis: a meta-analysis. *Br J Cancer* **110**:1878–1890.

Kopec JA, Esdaile JM (1990). Bias in case–control studies. A review. *J Epidemiol Comm Health* **44**:179–186.

Kurian AW, Balise RR, McGuire V, Whittemore AS (2005). Histologic types of epithelial ovarian cancer: have they different risk factors? *Gynecol Oncol* **96**:520–530.

Langseth H, Kjaerheim K (2004). Ovarian cancer and occupational exposure among pulp and paper employees in Norway. *Scand J Work Environ Health* **30**:356–361.

Langseth H, Hankinson SE, Siemiatycki J, Weiderpass E (2008). Perineal use of talc and risk of ovarian cancer. *J Epidemiol Community Health* **62**:358–360.

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, *et al.* (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol* **62**:e1–e34.

Lo-Ciganic WH, Zgibor JC, Bunker CH, Moysich KB, Edwards RP, Ness RB (2012). Aspirin, non-aspirin non-steroidal anti-inflammatory drugs, or acetaminophen and risk of ovarian cancer. *Epidemiol* **23**:311–319.

Merino MJ (2010). Malignant mesothelioma mimicking ovarian cancer. *Int J Surg Pathol* **18** (**Suppl**):178S–180S.

Merritt M, Green A, Nagle C, Webb P, Group ACSaAOCS (2008). Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer. *Int J Cancer* **122**:170–176.

Mills PK, Riordan DG, Cress RD, Young HA (2004). Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer* **112**:458–464.

Moorman PG, Palmieri RT, Akushevich L, Berchuck A, Schildkraut JM (2009). Ovarian cancer risk factors in African–American and White women. *Am J Epidemiol* **170**:598–606.

Mossman BT, Gee JBL (1989). Asbestos related diseases. *N Engl J Med* **320**:1721–1730.

Muscat JE, Huncharek MS (2008). Perineal talc use and ovarian cancer: a critical review. *Eur J Cancer Prev* **17**:139–146.

Ness RB, Grisso JA, Cottreau C, Klapper J, Vergona R, Wheeler JE, *et al.* (2000). Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiol* **11**:111–117.

Pike MC, Pearce CL, Peters R, Cozen W, Wan P, Wu AH (2004). Hormonal factors and the risk of invasive ovarian cancer: a population-based case–control study. *Fertil Steril* **82**:186–195.

Purdie P, Green A, Bain C, Siskind V, Ward B, Hacker N, *et al.* (1995). Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case–control study. *Int J Cancer* **62**:678–684.

Reid A, de Klerk N, Musk AW (2011). Does exposure to asbestos cause ovarian cancer? A systematic literature review and meta-analysis. *Cancer Epidemiol Biomarkers Prev* **20**:1287–1295.

Rohl AN, Langer AM, Selikoff IJ (1976). Consumer talcums and powders: mineral and chemical characteristics. *J Toxicol Environ Health* **2**:225–284.

Rosenblatt KA, Szklo M, Rosenheim NB (1992). Mineral fiber exposure and the development of ovarian cancer. *Gynecol Oncol* **45**:20–25.

Rosenblatt KA, Weiss NS, Cushing-Haugen KL, Wicklind KG, Rossing MA (2011). Genital powder exposure and the risk of epithelial ovarian cancer. *Cancer Causes Control* **22**:737–742.

Rothman KJ, Greenland S, Lash TL (2008). *Modern epidemiology*, 3rd ed. Philadelphia, PA: Lippincott-Wolters-Kluwer.

Schildkraut JM, Abbott SE, Alberg AJ, Bandera EV, Barnholtz-Sloan J, Bondy ML, *et al.* (2016). Association between body powder use and ovarian cancer: the African American Cancer Epidemiology Study (AACES). *Cancer Epidemiol Biomarkers Prev* **25**:1411–1417.

Stang A (2010). Critical evaluation of the Newcastle–Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. *Eur J Epidemiol* **25**:603–605.

Stanton MF, Layard M, Tegeris A, Miller E, May M, Morgan E, *et al.* (1981). Relation of particle dimension to carcinogenicity in amphibole asbestoses and other fibrous minerals. *J Natl Cancer Inst* **67**:965–975.

StataCorp (2015). *STATA/SE Vers 140 for Windows*. College Station, TX: StataCorp.

Terry KL, Karageorgi S, Shvetsov YB, Merritt MA, Lurie G, Thompson PJ, *et al.* (2013). Genital powder use and risk of ovarian cancer: a pooled analysis of 8525 cases and 9859 controls. *Cancer Prev Res* **6**:811–821.

Tzonou A, Polychronopoulou A, Hsieh CC, Rebelakos A, Karakatsani A, Trichopoulos D (1993). Hair dyes, analgesics, tranquilizers and perineal talc application as risk factors for ovarian cancer. *Int J Cancer* **55**: 508–510.

Wang V, Li C, Lin M, Welch W, Bell D, Wong YF, *et al.* (2005). Ovarian cancer is a heterogeneous disease. *Cancer Gen Cytogen* **161**:170–173.

Webb P, Gertig D, Hunter D (2008). Ovarian cancer. In: Adami HO, Hunter D, Trichopoulos D, editors. *Textbook of cancer epidemiology*, 2nd ed. New York, NY: Oxford University Press. pp. 494–516.

Wehner AP (1994). Biological effects of cosmetic talc. *Food Chem Toxicol* **32**:1173–1184.

Whittemore AS, Wu ML, Paffenbarger RS Jr, Sarles DL, Kampert JB, Grosser S, *et al.* (1988). Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am J Epidemiol* **128**:1228–1240.

Wong C, Hempling RE, Piver S, Natarajan N, Mettlin CJ (1999). Perineal talc exposure and subsequent epithelial ovarian cancer: a case–control study. *Obstet Gynecol* **93**:372–376.

Wu A, Pearce CL, Tseng CC, Templeman C, Pike MC (2009). Markers of inflammation and risk of ovarian cancer in Los Angeles County. *Int J Cancer* **124**:1409–1415.

Wu A, Pearce CL, Tseng CC, Pike MC (2015). African Americans and Hispanics remain at lower risk of ovarian cancer than non-hispanic Whites after considering nongenetic risk factors and oophorectomy rates. *Cancer Epidemiol Biomarkers Prev* **24**:1094–1100.